CHIMERAS AND HYBRIDS IN HUMAN PLURIPOTENT STEM CELL RESEARCH

A STUDY ON THE JURIDIFICATION OF NASCENT LIFE

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WAI LOON CALVIN HO

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Wai Loon Calvin Ho, J.S.D

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This dissertation presents an ethnographic study of the policy construction of animal chimeras and cytoplasmic hybrids in human pluripotent stem cell research by the Bioethics Advisory Committee (BAC) in Singapore. The principal methodology is in the style of actor-network theory as applied in the field of science and technology studies. A key objective of this research is to understand the relevance of law in the production of epistemic claims on pre-social and social life, and an explication of the mechanisms entailed. This dissertation also proposes a broadening of 'juridification' to mean the co-production of such claims by law, along-side other modalities of power, within a power-complex originally proffered by Michel Foucault as governmentality.

Law is defined in terms of legal notions, principles, forms and techniques. At one level, this dissertation examines the ways in which the law has been deployed by the BAC in constituting chimeras and hybrids as placeholders or models of 'Seeing As-If'. At another level, it examines the contribution of law in the scripting of a context or narrative that embeds these placeholders. The narrative or script is encapsulated within institutions and their documents, which are in turn intricately linked by particular relationalities. Contrary to prevailing accounts on legal

globalization, this dissertation reports a relationality that is less determinate and more open-ended among jurisdictions that share a policy position. An implement of law found to be ubiquitous in building relationality is comparative tables. Normative positions thereby established contribute not only to reflexivity (through interpretive sense-making for instance), but also instill a sense of solidarity (and division). Relationality is premised on anticipatory knowledge(s) centered around idioms of precaution and risks, which could be understood as legal forms (or analytics) that direct and justify policy decisions and actions.

Contrary to arguments of juridification as socially stifling (à la Gunther Teubner) or falling into irrelevance (from a limited reading of Foucault), this dissertation presents law as enabling and central to our experience of modernity. It also supports a less formalistic conception of law, particularly in the work of increasingly commonplace pseudo-juridical entities like the BAC.

BIOGRAPHICAL SKETCH

Wai Loon Calvin Ho is Assistant Professor at the Centre for Biomedical Ethics of Yong Loo Lin School of Medicine, National University of Singapore. Besides Cornell University, he read law at National University of Singapore, and University of Cambridge (England). While at Cornell, he also received training in science and technology studies and legal anthropology. In addition, he holds a bachelor's degree in economic sociology from the London School of Economics and Political Science, and a master's degree from the School of Oriental and African Studies (University of London), as well as a diploma in mathematical statistics. He practiced law in London and Singapore, and was Senior Research Associate with the Bioethics Advisory Committee, an expert body appointed by the government of Singapore to provide advice and recommendations on human biomedical research. Calvin's research interests include environment conservation, access to health, research policy analysis, property and intellectual property rights, informational confidentiality and privacy, and research integrity. He is an avid bird-watcher and has hugged trees.

For my Family

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My fieldwork in Singapore would not have been possible without the support of the immediate past Chairman of the Bioethics Advisory Committee (BAC), Professor Lim Pin, and my former colleagues at the Secretariat, namely Dr. Sylvia Lim, Professor John Elliott, Ms. Charmaine Chan and Mr. Alvin Chew. I cannot sufficiently express my gratitude for their kindness, encouragement and support. I especially thank Sylvia, for our many conversations and collaborations since the founding of the BAC. The past and present members of the BAC, its working groups and its International Panel of Experts have also been exceptionally generous and kind in sharing their views and experiences. I record my deep thanks to them. I also extend my

gratitude and thanks to all whom I interviewed, for our conversations and documents that they shared with me.

Finally, my family has been a constant source of inspiration, encouragement and support. This work is dedicated to you: Mum, Dad, Claudia, Takamitsu, Mika and Hazel. Last but not least, I also extend my deepest thanks to Karel Caals and Marc Certenais for their encouragement and support.

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LIST OF ABBREVIATIONS

AMS	Academy of Medical Sciences (UK)
ANT	Actor-Network-Theory
AR Directives	Directives for Private Healthcare Institutions Providing Assisted Reproduction Services, MOH, March 2006 (Revised)
ART	Artificial Reproductive Technologies
A*STAR	Agency for Science Technology and Research (Singapore)
AVA	Agri-Food and Veterinary Authority (Singapore)
BAC	Bioethics Advisory Committee (Singapore)
CIRM	California Institute for Regenerative Medicine
DCE	Danish Council of Ethics
DHHS	Department of Health and Human Services (US)
ED	Egg Donation (Consultation Paper and Report)
ELSI	Ethical, Legal and Social Implications
EPA	Environment Protection Agency (US)
ESCRO	Embryonic Stem Cell Research Oversight (US)
EU	European Union
HAC	Human-Animal Combinations (Consultation Paper and Report)
hES(C)	Human Embryonic Stem (Cell)
HECR	Human Embryo and Chimera Research Working Group (of the BAC)
(HFE)A	(Human Fertilisation and Embryology) Authority (UK)
HSCR	Human Stem Cell Research Sub-Committee of the BAC (Singapore)
IACUC	Institutional Animal Care and Use Committee
IFFS	International Federation of Fertility Societies

IOM	Institute of Medicine (US)
iPSC	Induced Pluripotent Stem Cell
IRB	Institutional Review Board
IRGC	International Risk Governance Council
ISSCR	International Society for Stem Cell Research
IVF	*In-vitro* Fertilization
MOH	Ministry of Health (Singapore)
NACLAR	National Advisory Committee on Laboratory Animal Research (Singapore)
NAE	National Academy of Engineers (US)
NAS	National Academy of Sciences (US)
NBAC	National Bioethics Advisory Commission (US)
NRC	National Research Council (US)
NUS	National University of Singapore
OHSS	Ovarian Hyper-stimulation Syndrome
SCLS	Steering Committee on Life Sciences, Singapore Cabinet
SCNT	Somatic Cell Nuclear Transfer
SC Report	Stem Cell Report of the BAC published in 2002
SCRO	Stem Cell Research Oversight
STS	Science and Technology Studies
UK	United Kingdom
UN(GA)	United Nations (General Assembly)
US	United States of America

CHAPTER 1

GOVERN STEM CELLS, GOVERN LIFE

Abstract

This research proposes a broader and less formalistic definition of juridification as co-production of epistemic claims on social and pre-social life by `law, as legal norms, techniques and practices that are not limited to strictly governmental agents and institutions. As an ethnographic study of the work of the BAC in the bioethical construction of animal chimeras and cytoplasmic hybrids, the socio-historical context is briefly set out in this chapter. In addition, an overview of the knowledge systems (formal and anecdotal), cognitive forms, materials and social relations entailed in the juridification of nascent life is provided. On methodology, it is argued that interactive engagement with field subjects is preferable to a more 'removed' approach encompassing participant observation and interviews. However, there is a greater need for reflexivity, particularly in the research representations advanced and in addressing double binds. It is argued that ethnography in the style of ANT/STS (and incorporating aspects of the para-ethnographic) is especially suitable, since this study proposes that 'law' cannot be neatly separated from other knowledge fields, and that the repository of 'agency' is distributed in different localities within power and knowledge structures. It is further argued that ANT/STS methodology supports a multi-sited approach, and for this research, a deep textual reading of documents.

1.1 Why Study Juridification?

At the turn of the century, policymakers in Singapore earmarked biomedical sciences as a driver for its continuing economic growth. The technological edge that it hopes to develop is expected to insulate its thriving pharmaceutical and healthcare industries from increasing competition. Positive externalities from the investment are expected to include strengthening Singapore's standing as a regional education hub. Among the various initiatives adopted in furtherance of this goal was the establishment of the Bioethics Advisory Committee (BAC) in December 2000. A key responsibility of the BAC has been to assist the government in establishing an appropriate regulatory environment. The first regulatory regime that the BAC put in place concerns human embryonic stem cell research, primarily through the publication of a set of ethical recommendations (the SC Report) in 2002.[1] This report contributed to the enactment of legislation on cloning[2] and the issuance of a revised set of directives on ARTs by the MOH (AR Directives). In 2006, shortage of human eggs needed for research, along with technological developments (particularly concerning iPSCs) necessitated a review of its recommendations. Following a period of research, deliberation and consultation, the BAC published a new set of ethical guidelines on donation of human eggs for research in 2008 (the ED Report),[3] and another set of guidelines on human-animal combinations in 2010 (the HA Report).[4]

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1 Bioethics Advisory Committee, Singapore, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*. Singapore: Bioethics Advisory Committee, June 2002.

2 Singapore Statutes: *Human Cloning and Other Prohibited Practices Act* (Cap. 131B), Revised 2005.

3 Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, November 2008.

4 Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010.

This dissertation is a study of the juridification of nascent life, brought about with the publication of the ED Report and the HA Report. Juridification is conventionally understood as "a process (or processes) by which the state intervenes in areas of social life…in ways which limit the autonomy of individuals or groups to determine their own affairs. In the most general terms, it is about the relation between state and society, and the balance between their relative influence on the way human beings conduct their lives."[5] More precisely, the notion of juridification is directly concerned with the proliferation of law, especially regulatory law, and it relates to Max Weber's 'materialization of formal laws'.[6] My use of the term is less formalistic; not quite as Teubner would deploy it, but one that he arguably does not preclude. As with a number of other contemporary works, I have found that 'juridification' in terms of legal rules, norms and culture is not limited to strictly governmental sources, but extend beyond the state. This broad definition is necessary because juridification cannot be explained by the regulatory mentalities (or 'regulationism') of the state alone.[7] In addition, I did not find juridification to be necessarily limiting of liberty interests – at least not in the non-formalistic operation of law. Rather, the notion of co-production in STS may be a more apt depiction of legal contribution to policy development in the context of my research, and 'juridification' is only intended to show the indispensable role of law (a more in-depth discussion of this point is presented in Chapter 6). In this dissertation, I explain the ways that meanings, functions and constructions of law and legal techniques have been taken up in policy and scientific environments. Through working in the

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5 Jon Clark and Lord Wedderburn, Juridification – a Universal Trend? In Gunther Teubner (ed), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labor, Corporate Antitrust and Social Welfare Law*. Berlin: Walter de Gruyter & Co., 1987, pp 163-190, at 165.

6 Gunther Teubner, Juridification – Concepts, Aspects, Limits, Solutions. In Gunther Teubner (ed), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labor, Corporate Antitrust and Social Welfare Law*. Berlin: Walter de Gruyter & Co., 1987, pp 3-48, at 4-5.

7 A similarly broad approach to juridification has been adopted by Javier Couso and others: Javier Couso, Alexandra Huneeus and Rachel Sieder, *Cultures of Legality: Judicialization and Political Activism in Latin America*. Cambridge: Cambridge University Press, 2010.

field of bioethics, I ask: What is 'legal' about bioethics? What are the ideas and artifacts that bioethics encompasses, and how are they related to law? How do ideas move from one knowledge system to another? In particular, what is the role of law in bioethics?

As the BAC has been the leading actor in the institutionalization of bioethics in Singapore, it was the primary subject of my ethnographic study from October 2007 to September 2010 (Diagram 1 illustrates the structure of the BAC). Bioethics encompasses many varied aspects and processes concerning life, from synthetic biology to climate change. In a formal sense, the contribution of the BAC to this discourse arises from considering the ethical, legal and social implications of life sciences advancements. During the time that my research was carried out, the BAC was formulating recommendations for chimeras and hybrids – biological constructs that are now indispensable to many types of biomedical research. Hence my research is also about the historical and situational context within which regulations relating to chimeras and hybrids have emerged in Singapore. Given the relatively lengthy duration of the study, my involvement has been as a member of its Secretariat, rather than an impartial and indifferent participant-observer, or as some might say, 'a fly on the wall'. As legal researcher with the Secretariat, my responsibility has been to facilitate the work of the BAC from the standpoint of law. Following Annelise Riles[8] and Mitchell Lasser,[9] I examine the application of legal technicalities and

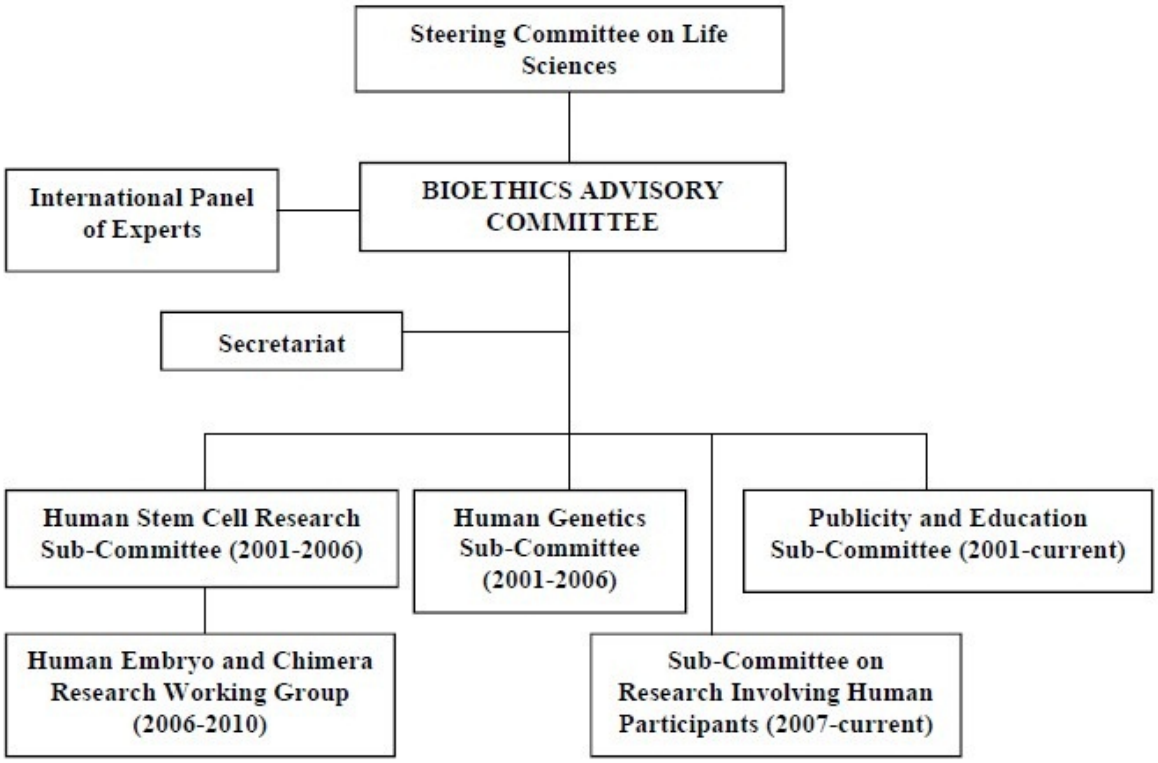
[8] I draw significantly on Riles's two key works, *The Network Inside Out* and *Collateral Knowledge*, both of which will find repeated references in the dissertation. Both these works present innovative application of Actor-Network Theory and ethnography in the study of knowledge fields. See Annelise Riles, *The Network Inside Out*. Ann Arber: University of Michigan Press, 2001; and Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 11-14.

[9] Lasser's *Judicial Transformation* provides a dynamic account of the transition of the French legal system from a paradigm of republicanism to one that is based on fundamental rights. The analysis undertaken avoids presenting the French legal system as monolithic, static or self-contained. While there are some features of the French legal system that have not changed, such as the Civil Code which dates back to the Napoleonic era, Lasser demonstrates that French legal and political institutions and theory have evolved over time. Mitchel de

rationalities to non-legal fields. Within the discipline of law, one might ask: Is there such a thing as law on chimeras and hybrids (or more generally, human pluripotent stem cells)? Perhaps it is as transient, or perhaps even illusory, as the "law of the horse".[10] And if it exists, what are the legal rationalities and techniques that have been deployed to bring about their construction and subscription? Does this development deserve study? Why should Singapore law matter at all?

S.-O.-l'E. Lasser, *Judicial Transformations: The Rights Revolution in the Courts of Europe*. Oxford and New York: Oxford University Press, 2009, at 10.

[10] Lawrence Lessig, The Law of the Horse: What Cyberlaw Might Teach. *Harvard Law Review* (1999) 113:501.



Terms of Reference

The BAC has two main roles:

(1) Examine ethical, legal, and social issues arising from research on human biology and behaviour and its applications; and

(2) Develop and recommend policies to the Steering Committee on Life Sciences on these issues.

The BAC has three priorities:

1. Protection of the rights and welfare of individuals;
2. Public education & a source of information on bioethical issues; and
3. Identify broad principles to govern the ethical, legal and social implications of human biomedical research.

Diagram 1. The Organization Structure of the BAC and its Terms of Reference

Just as Riles has studied the practices surrounding the governance of the global financial markets through one motif (ie the 'collateral'),[11] I adopt and adapt her approach in studying technical or 'knowledge practices' that constitute the governance of biomedical research in Singapore, and attempt to explicate some of the often taken-for-granted 'facts' that policymakers and regulators apply when, say, preparing and putting forward guidelines and recommendations. I also find that human-animal combinations – principally hybrids and chimeras – constitute a useful motif in studying the governance of biomedical research for a number of reasons. First, it is directly related to stem cell research, which has profoundly influenced the *mentalité* of policymakers and regulators on the nature of 'bioethical' issues, as well as the means by which they could be responded to. Second, the very controversial character of stem cell research highlights the role or function of law in engaging with the contentions. It is further instructive as to how policymakers and regulators have reacted to a controversy, and their actions could illustrate how they think about law and governance more generally. Third, human-animal combinations present the most contentious set of issues arising from stem cell research at the time of this research. They are also 'boundary objects', which enable the study of how different knowledge fields interact.[12]

I show that the law relating to stem cell research exists in the form of legal rationalities and technicalities with coherence and values that are distinct from the major (and formal) branches of law such as law of property or intellectual property. I argue that studying how law connects with chimeras and hybrids can provide useful insights on how the law works vis-à-vis science and technology and its contribution to the broader discourse of bioethics. By asking, as Annelise

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11 Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 224.

12 Susan Leigh Star, This is Not a Boundary Object: Reflections on the Origin of a Concept, *Science, Technology, & Human Values* (2010) 35, 5: 601-617.

Riles does, "what are chimeras and hybrids, really, in biomedical research?",[13] one can begin to appreciate how these constructs illustrate the legalization of hybrid life.[14] It further allows us to question:[15] "Who is in control? Who is responsible for what? Could anyone take control? And to what end?"

Bioethics is concerned with more than scientific research. It is an assemblage of "many forms of expertise and many kinds of technology" in different domains.[16] Developments in Singapore reflect a broader trend of similar developments in leading scientific jurisdictions. Arguably, these developments are linked to those occurring in transnational and international discursive spaces. Notably, regional groupings, such as the EU, and international associations on stem cell research have also been agents of change. By studying the current changes in law and bioethics in Singapore, one can better appreciate the substance and direction of similar developments elsewhere.[17] The converse is also true. Changes in Singapore can be better understood through studying parallel or related developments elsewhere.

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13 Riles suggests that "if one approaches regulatory debates from the standpoint of the deceptively naïve question, "what is collateral, really in the derivatives markets?" one begins to grasp a view of regulation as something very different…": Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 10. Lessig's observation that the law in its traditional sense – as an order backed by threat – is one of many tools that constrain behaviour, as well as law's impact on these other tools, is helpful: Lawrence Lessig, The Law of the Horse: What Cyberlaw Might Teach, *Harvard Law Review* (1999) 113:501, at 502.

14 Annelise Riles. A New Agenda for the Cultural Study of Law: Taking on the Technicalities, *Buffalo Law Review* (2005) 53: 973-1033. Riles observes (at 973) the need to increase our "understanding of the very thing that defines our field, of what makes law as opposed to literature or economics or cognitive science: the technicalities of legal thought." She adds that as lawyers, the notion that law is more than just rules have not stopped "lawyers from loving their tools for their own sake…from having a certain aesthetic appreciation for their uses. What defines the technical as a sphere of social practice, in other words, is lawyers' commitments to an aesthetic of instrumentality, not simply to an instrumentalist politics or project" (at 1026).

15 Sally Falk Moore. *Law and Anthropology: A Reader*. Cornwall: Blackwell Publishing, 2005, at 3.

16 Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 11. Just as markets are made up of more than finance, the varied expertise that makes up the BAC is illustrative of a similar plurality in bioethics.

17 I see this as parallel to Lasser's argument that serious attention will have to be paid to developments at the level of national legal systems, if only to gain a better understanding of the dynamics between developments on

Studying developments in Singapore is important for other reasons. Susan Silbey and Patricia Ewick show the power of law in the minds of common people.[18] Indeed, this dissertation lends support to their finding that the law has a vivid existence outside of the "enchanted rationality" of legal scholars, judges and lawyers.[19] It takes varied forms in different cultural schemas or images and invokes different normative claims, justifications and values.[20] Yet in all of these accounts, there is a certain stability of meaning – even if fragmentary. How is this achieved? This dissertation suggests that outside the "enchanted realm", commoners understand both law and bioethics normatively.[21] In most respects, bioethics will be viewed no differently from law. I attempt to provide accounts of the mechanics by which these normative accounts of law (legality) and bioethics (ethical) are associated and stabilized. By examining the interaction and movement of ideas between law and other knowledge systems as diverse as ethics, medicine and science, the character and role of legal norms become more explicit.[22] In examining legal norms, I also attempt to explicate the techniques that are applied in a public policy environment. Some of these techniques are closely associated with legal norms and practices, whereas others will have a broader normative basis. These 'techniques' are artifacts that Annelise Riles regards as "means, not ends – they are not tethered to any particular policy outcome or political point of view",[23] which she describes as "placeholders, documents, theories, dreams, fictions, analogies,

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the domestic and supranational levels: Mitchel de S.-O.-l'E. Lasser, *Judicial Transformations: The Rights Revolution in the Courts of Europe*. Oxford and New York: Oxford University Press, 2009, at 13-14.

18 Susan S. Silbey and Patricia Ewick. The Double Life of Reason and Law, *University of Miami Law Review* (2003) 57: 497-512.

19 *Ibid* at 503.

20 *Ibid* at 506.

21 This should come as no surprise as Hans Kelsen has postulated that the law is in essence a system of norms. See Hans Kelsen. *Pure Theory of Law*, (2nd edition, Trans. M. Knight). Berkeley and Los Angeles: University of California Press, 1967.

22 Annelise Riles. Representing In-Between: Law, Anthropology, and the Rhetoric of Interdisciplinarity, *University of Illinois Law Review* (1994) 597-650.

23 Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 229.

and many others…"[24] With Riles, the core aspects of juridification are identified in its epistemology, its aesthetics, its materiality, and its virtual sociality,[25] rather than a formalistic and limited conception of juridification only as expansion of sovereign power. In this study, legal (and ethical) norms, practices and techniques have served as means to objectify and fabricate, create a script or narrative, enable comparison, conceptualize and reconcile with risks, and create (or otherwise privilege certain) mindsets and rationalities.

1.2 The Honest Broker

Prior to the establishment of the BAC, formal ethics review of biomedical research was somewhat of a novelty, except in the well established procedures for the regulation of clinical drug trials. BAC's Deputy Chair, Lee Hin Peng, recalled that he was responsible for setting up an *ad hoc* IRB of NUS when he was the Principal Investigator of a research with American collaborators in 1992.[26] This project-specific *ad hoc* IRB was established to satisfy a requirement of funding by the US National Cancer Institute, that research carried out in Singapore be reviewed by a local IRB. It was not until 2003 that NUS established its own IRB with himself as its Chair.

Outside of NUS, ethics review was largely informal (up until 2004) even though the profound impact of ethics on biomedical sciences was already being felt from the 1960s onwards.

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[24] *Ibid*, at 228.

[25] Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 230.

[26] Interview with Professor Lee Hin Peng, 27April 2009. Professor Lee was Deputy Chair of the BAC from 2007 to 2010.

Increasingly, the legitimacy of biomedical sciences depends not only on methodological rigor, but also on the ethical acceptability of their goals and applications.[27] Edison Liu captures the essence of this in his remark, "Science in the absence of humanity is not only irrelevant but dangerous".[28] He explained that science must be consistent with the fundamental values of society as it can be a destructive force if misapplied. Patrick Tan, a biomedical researcher, made a similar point in his observation that 'good science' is also a matter of assessing how far scientific pursuit can be justified within an existing system of norms and values.[29] He considered a goal of science to be pushing against knowledge boundaries,[30] so that like 'good art', 'good science' must not only be unquestionable in terms of its intellectual base or rigor, its results and impact must also extend beyond the present. But where a scientific postulation has profound impact on social norms and values, most scientists tend to be wary about pushing too far.

Patrick Tan went on to observe that apart from broader society, scientists are also embedded within their own communities. Due to this and possibly also to the need for funding, scientists tend to be socially conservative by nature and mavericks are rare.[31] 'Good science' emerges as 'spikes' out of the communal effort of smart people working together on an idea within a suitable milieu. Ethical values are important for scientists within their own community, and in their relationship with broader society. As Marilyn Strathern argues, ethics may be understood as

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27 Maureen Kelley, Craig Rubens and the GAPPS Review Group. Global report on preterm births and stillbirth (6 of 7): ethical considerations. *BioMed Central Pregnancy and Childbirth* (2010) 10, Suppl. 1, S6: 1-19, p 1.

28 Interview with Professor Edison Liu, 8 July 2009. Professor Liu served on the BAC from 2003 to 2006. He was Executive Director of the Genome Institute of Singapore, a key research institution in Singapore.

29 Interview with Associate Professor Patrick Tan, 26 June 2009. Associate Professor Tan has been a member of the BAC since 2007.

30 Dr Lim Bing expressed a similar view. He felt that biomedical research is about "pushing against boundaries", although scientists in general value life. He himself considers all life to be valuable. Interview with Dr Lim Bing, 13 July 2009. Dr Lim was a member of the HECR Working Group from 2006 to 2010.

31 Philosopher Nuyen Anh Tuan also observed scientists to be socially more conservative than he thought prior to his experience with the BAC. Interview with Associate Professor Nuyen Anh Tuan, 21 April 2009. Associate Professor Nuyen was a member of the BAC since 2005.

'personal' responsibilities, rights and liabilities which are drawn from more general social sensibilities embedded in all kinds of human interactions and moralities. Consequently, the ends of ethical conduct ensure that, as means, they meet certain criteria in themselves.[32]

Recognition of juridification in biomedical research has been slow largely due to the perception that law always lags behind scientific and technological advancement. Hence prior to 2000, there was not much of a 'governmentality' to speak of, as researchers were generally trusted to do the right thing. However, this was to change for two key reasons. First, interest and investment by the state created a need to ensure that results are measurable and recognized internationally. Lee Eng Hin, who was Dean of Singapore's (then) only medical school at NUS in 2000, said that the government recognized how intricately biomedical sciences have become intertwined with ethics.[33] Having considered a number of national ethics bodies in the English-speaking world, the BAC was appointed by the government to guide its policies on developing the nation's biomedical research capabilities within an ethical and social normative framework that is acceptable both locally and internationally. He indicated that there was some urgency in fully operationalizing the BAC as biomedical research activities had increased exponentially and there was a need to establish clear ethical guidelines for such research especially in the controversial area of human embryonic stem cells. For Singapore's research findings to be accepted internationally it was extremely important for Singapore to have a robust ethical framework. Ethical direction and consistency are further important in sustaining the legitimacy and

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[32] Marilyn Strathern. Accountability…and ethnography. In Marilyn Strathern (ed), *Audit Cultures: Anthropological studies in accountability, ethics and the academy*. London: Routledge, 2000, pp 279-304, at 292-293.

[33] Interview with Professor Lee Eng Hin, 9 April 2009. Professor Lee was a member of the BAC from 2005, until his appointment as Executive Director of the Biomedical Research Council of the Agency for Science Technology and Research in 2008.

commitment for an uncertain long term venture taken up in the interest of the common good. Tan Chorh Chuan, who was Director of Medical Services (or Chief Medical Officer) at that time, indicated that the government also recognized that the public must be comfortable with the pace of progress in biomedical sciences, which would accelerate with the adoption of the biomedical sciences initiatives.[34] Hence, the work of the BAC was not limited to advising the government, but also to promote public trust. In particular, the BAC had the critical task of facilitating public deliberation of bioethics issues through appropriate framing of bioethical issues and the provision of accessible and factually accurate information which served as a starting point for discussion.

Second, scientific endeavor has moved into a highly politicized area so that scientists did not have the necessary institutional resources to manage. Understandably, there was no specific regulatory framework for embryo research (but only in relation to ARTs) prior to scientific interest in stem cells. However, due to subsequent and rapid developments in the field and the public interest it has drawn, a comprehensive and formal assessment as to its ethical, legal and social implications was deemed necessary in order to enable the science to move forward. The Chairman of the HSCR Subcommittee, Richard Magnus (then Senior District Judge), said that the BAC decided to take up embryonic stem cell research and cloning for consideration because it was at that time the most controversial area of biomedical research.[35] Already controversial in certain local quarters, stem cell research and cloning were widely publicized by events such as the announcement by then US President George W. Bush on 9 August 2001, to deny federal

[34] Interview with Professor Tan Chorh Chuan, 4 May 2009. Professor Tan was Director of Medical Services, as well as a member of the BAC, from 2001 to 2004. He was then Provost and subsequently the President of NUS.

[35] Interview, 18 April 2009.

funding for research on stem cells derived from embryos created after 10 August 2001.[36] In Singapore, public expression of concern over the practice of embryonic stem cell technology was received by the BAC as soon as its website was launched on 22 August 2001.[37] Cloning also became a subject for debate at the UN in 2001. When I asked how he managed seemingly irreconcilable differences on the subject, Richard Magnus, said that his experience in legal adjudication has been beneficial in that mediating disagreements in an impartial manner.

The Chairperson of the BAC, Lim Pin, agreed.[38] When I asked how the BAC decided on its first subject matter for deliberation, he said that it was circumstantial. Judge Magnus added that the BAC decided to prioritize its deliberation on stem cell research and cloning because of local research interest in the field. There was also a need to clarify Singapore's position as political contention over the subject intensified.[39] Ng Soon Chye said that local researchers had been involved in IVF-related embryo research for some time. He was himself working with Ariff Bongso on embryo research, and was also interested in therapeutic cloning involving primates.[40] In 2000, the establishment of ES Cell International which aims to develop therapies from human embryonic stem cells drew public attention to Singapore's engagement in this ethically contentious area of embryonic stem cell research. In the year that followed, the then US President George W Bush limited public funding to certain established embryonic stem cell lines and (as we have considered above) an international treaty to ban cloning was being considered

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36 Office of the Press Secretary. *Remarks by the President on Stem Cell Research*. 9 August 2001.

37 Ailien Chang. Stem-Cell Research Draft Guidelines Out Next Month. *The Straits Times*, 13 September 2001.

38 Interview, 27 April 2009.

39 Interview with Mr Richard Magnus, 18 April 2009. As noted, Mr. Magnus was Chair of the HSCR Subcommittee from 2001 to 2002, and remained a member of the BAC until 2006 (he was also Deputy Chairman from 2005 to 2006. He was re-appointed to the BAC in 2009, and became Chairman of the BAC from 2011.

40 Interview with Professor Ng Soon Chye, 26 May 2009. Professor Ng was a member of the BAC from 2009. Prior to that, he was a member of the HECR Working Group from 2006 to 2010.

by the UN. Not surprisingly, many past and present BAC members consider human embryonic stem cell research and cloning to have been the most ethically contentious subject that the BAC considered. By the time between the 56th UNGA and the first meeting of its Ad Hoc Committee, the BAC arrived at an interim ethical position on the subject, and public consultation commenced on 8 November 2001. While the BAC reasoned that reproductive cloning of human beings should be prohibited, embryonic stem cell research and therapeutic cloning was considered to be ethical provided that these proceed on a strictly regulated basis and subject to particular ethical requirements (primarily the 14-day rule). This ethical stance has been encapsulated in the SC Report, and it represents the juridification of nascent *human* life. I should emphasize that both Chairman Lim Pin and Judge Magnus acknowledged the legal skill of mediating among adversarial viewpoints as having contributed to the success of the SC Report. This is but one instance where adversarial legalism has moved beyond its legal environment and into a bioethical one.[41]

As work that comes within the genre of public bioethics,[42] the BAC's limited epistemology of life acts in direct competition with some religious foundational viewpoints. For instance, the views of the main religions in Singapore on hESC research (set out in Table 1)[43] are not necessarily consistent with that of the BAC. During the period of this research, the BAC was composed of senior civil servants (some of whom legally trained), biomedical researchers,

41 For a discussion on adversarial legalism and responsive regulation, see David Levi-Faur, The Political Economy of Legal Globalization: Juridification, Adversarial Legalism, and Responsive Regulation. A Comment. *International Organization* (Spring 2005) 59: 451-462.

42 John H. Evans. Between Technocracy and Democratic Legitimation: A Proposed Compromise Position for Common Morality Public Bioethics, *Journal of Medicine and Philosophy* (2006) 31: 213-234; and Adam Hedgecoe. Bioethics and the Reinforcement of Socio-technical Expectations, *Social Studies of Science* (2010) 40, 2: 163-186.

43 Sylvia Lim and Calvin Ho, The ethical position of Singapore on embryonic stem cell research. *SMA News* (2003) 35, 14: 21-23, at 22.

academicians (including an ethicist and a philosopher), physicians and the editor of the main English language newspaper in Singapore. Professor Lim Pin, the Chairperson, has been the longest serving Vice-Chancellor (now called President) of NUS. To the extent that the news bureau and the two local universities (with which many of the members were affiliated) could still be regarded as 'public' institutions (as they have been formally 'privatized'), the BAC is a pseudo-government (arguably pseudo-juridical) establishment. More importantly, this would be consistent with public perception, as its members would easily be recognized as senior bureaucrats. However, the BAC is *not* a bureaucracy (in a Weberian sense), in that its task was not to devise or implement policies. Instead, it has the dual role of being an advisor to the government and a mediator between the government and relevant stakeholders. In fact, the purpose of constituting the BAC outside of 'formal government' is to secure for it a level of independence.

Table 1. Religious Views on Embryonic Stem Cell Research and Cloning in Singapore

Religious Group	Embryonic Stem Cell Research	Therapeutic Cloning	Reproductive Cloning
Baha'I	"… affirm that the human soul comes into being at the time of conception." But the exact moment and nature of events in conception is a mystery. Believers who are faced with complex ethical questions are "free to come to their own conclusions" but "should be careful not to make dogmatic statements or offer their own understanding as the teachings of the Faith."		
Buddhist	For "Support research on human stem cell that will benefit humankind as a result"	For	Against
Catholic	Against "The human being is to be respected and treated as a person from the moment of conception; …"	Against	Against
Christian	Against "cloning of human beings should be banned unequivocally …" "Opposes stem cell research using human embryos."	Against	Against
Hindu	For "… killing a foetus is a sinful act" but "whether the 14-day old foetus is endowed with all the qualities of life is not well regarded. Therefore, there is no non-acceptance to use ES cells to protect human life and to advance life by curing diseases."	No specific comment received	No specific comment received
Jew	For "… a fetus prior to forty days gestation is not considered to be an actual person ..."	Unclear but "likely that Rabbinic authorities will not favor such a leniency."	No specific comment received
Muslim	For "An embryo is only considered as a human life after it is 4 months" when "a soul is introduced …"	For	Against
Sikh	Against "… human life begins when the male and female living cells unite" and "totally respects the sanctity of the Gift of Human Life by God ..."	Against	Against
Taoist	Against "… not supportive of research that … goes against nature, and that involves the killing of another life, eg using embryos for research."	Against	Against

Even then, there was a general sense of futility among BAC members that certain segments of society would dismiss the BAC as a government 'mouthpiece'. However, a few BAC members indicated that the current arrangement ensured that recommendations of the BAC would be taken seriously by the government, particularly by the member's own department or organization. For instance, the MOH would not lightly dismiss the BAC's advice given that the Director of Medical Services (being the third most senior figure in the Ministry after the Minister for Health and the Permanent Secretary) has signed off on it. If the BAC was entirely independent of the government, the latter would probably be less willing to accept any advice proffered for a number of reasons, including skepticism of hidden agenda, feasibility and propriety across different levels. Ironically, it was also this strong link to (but at the same time separation from) the government that underscored public confidence in the recommendations of the BAC. A broad sense of neutrality in the pursuit of 'public interest' could account for the exclusion of religious or industrial representation on the BAC. Indeed, many BAC members pointed out that the BAC should avoid being perceived as promoting research for commercial gain or otherwise advancing a particular (specifically, religious) point of view. When asked, almost all BAC members indicated a key role of the BAC to be the provision of fair and independent advice on protecting the welfare of human research subjects.

During my interviews with the BAC members, they also consistently recognized that in operating 'outside' of government, their appointment on the BAC was not an extension of their official positions. Instead, their role has been to determine and guide the actions of government in ways that meet the requirements of 'good science', primarily through the provision of advice. The advisory nature of the BAC's work should not be under-estimated as it reinforced the

intended independence. Since any advice of the BAC would not be technically binding on the government, the members did not consider themselves to be doing or influencing 'politics'. At the same time, they also did not consider themselves to be technicians (or technocrats) in that no member (save one) considered himself or herself to be a professional ethicist. This is not to say that the BAC members were unfamiliar with ethical discourses, rationales and practices, or that their contributions have been insignificant. Even then, many BAC members considered their contributions to be 'trivial'. There may be a number of reasons for such a sentiment. First, the Secretariat has been mainly responsible in crafting the proposed recommendations with the Working Group and the BAC Chairperson. As we shall see, the situation in Singapore has not been so different from other jurisdictions included in this research. Second, the work of the BAC did not draw directly on the individual expertise of the members, or only tangentially at best. Third, no grand theories were discussed nor was there any deep and intense philosophizing in any of the BAC's meetings. It was not uncommon that the information exchanged within the BAC, and between the BAC and its Secretariat, both in and outside of formal meetings, had an anecdotal character.

Far from trivial, the Secretariat depended heavily on such anecdotal information in steering both the orientation and substance of the work. Each BAC member was deeply embedded in their respective communities, both locally and overseas. For instance, leading physicians on the BAC have been well attuned to research sentiments on the ground from their day-to-day interactions with patients and their colleagues in the biomedical research community. Similarly, researchers on the BAC have provided insightful 'real time' information on challenges that confronted the research community, such as the bureaucratization of research or the greater emphasis on

industrial collaboration.[44] While the BAC members were very aware of the ethical requirements and what the ethical environment ought to look like, they also understood the reality of practical challenges and constraints. I find this description of Alan Greenspan by Douglas Holmes and George Marcus to aptly depict many of the BAC members (in a biomedical rather than economic context): "someone shaped in sensibility and habitus by the routines of economic discipline, partial to its formalities, yet distinctively in rebellion to its conventional wisdom and guidance".[45] A similar set of sensibilities, intuitions (or habitus) and relationalities underscore the tremendous experiential value of anecdotal information provided by the BAC members, as Holmes and Marcus have observed in regulating financial markets:[46] "…from their [ie bureaucratically power officials like Greenspan] privileged networks of relationships these subjects can construct representations of the economy, drawn from experiential material that is fundamentally different from those representations that arise through the application of the statistical modes of analysis. Again, what makes these anecdotal accounts something more than merely another form of "information" or "data" is their social character – mediated through networks of interlocutors – conferring on these accounts distinctive authority can inform policy formulation and action." This research corroborates the finding of ethnographers like Douglas Holmes, George Marcus and Annelise Riles in their works on financial markets that anecdotal

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44 Annelise Riles, Real Time: Unwinding Technocratic and Anthropological Knowledge. In Melissa S. Fisher and Greg Downey (eds), *Frontiers of Capital: Ethnographic Reflections on the New Economy*. Durham and London: Duke University Press, 2006, pp 86-107.

45 Douglas R. Holmes and George E. Marcus, Cultures of Expertise and the Management of Globalization: Toward the Re-Functioning of Ethnography. In Aihwa Ong and Stephen J. Collier (eds), *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems*. Singapore: Blackwell Publishing, 2005, pp 235-252, at 240.

46 *Ibid*, at 246.

information is critically important to understand tacit knowledge in governance,[47] and further illustrates the value of ethnography as a methodology.

1.3 Fieldwork and Ethnography

It is within the historical and socio-political context revolving around the SC Report that my ethnographic research has been conducted between August 2007 and September 2010. Carol Greenhouse defines fieldwork as a relational practice linking knowledge production to the historical and local specificity of experience. In this connection, she considers field studies of law to make a broad subject because of their quantity and variety, as well as the mutual embeddedness of legal and social concepts.[48] Ethnography is a means by which the mutual embeddedness of scientific and social concepts has been studied by social scientists. For instance, Jeanette Edwards, Penny Harvey and Peter Wade indicate that anthropologists "work ethnographically, looking at how connections are made and unmade between persons, on what terms and with what effects."[49] Ethnography is my methodology. As a means of open-ended inquiry, it has the capacity to represent complexity in a manner that is least reductionist, and

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47 Douglas R. Holmes and George E. Marcus, Fast Capitalism: Para-Ethnography and the Rise of the Symbolic Analyst. In Melissa S. Fisher and Greg Downey (eds), *Frontiers of Capital: Ethnographic Reflections on the New Economy*. Durham and London: Duke University Press, 2006, pp 33-57; and Annelise Riles, Real Time: Unwinding Technocratic and Anthropological Knowledge. In Melissa S. Fisher and Greg Downey (eds), *Frontiers of Capital: Ethnographic Reflections on the New Economy*. Durham and London: Duke University Press, 2006, pp 86-107.

48 Carol J. Greenhouse, Fieldwork on Law. *Annual Review of Law and Social Sciences* (2006) 2:187-210, at 187.

49 Jeanette Edwards, Penny Harvey and Peter Wade. *Anthropology and Science: Epistemologies in Practice.* Oxford: Berg, 2007, at 6.

thereby maximize interpretive flexibility.[50] Rose, O'Malley and Valverde indicate that ethnography is aptly suited for analyzing governmentality by virtue of these characteristics.[51] Cris Shore adds that the ethnographic method is effective for the study of 'elites' because they form parts of wider encompassing culture but are not readily accessible.[52] In addition, he indicates that "when studying elites we should be cautious about generalizing from the micro to the macro. What happens at the local level is not a microcosm of, or synecdoche for, processes and formations occurring at the national or global levels. Even within a shared social system or political culture, elites and masses occupy a very different habitus."[53] Ethics, law, medicine, public policy and the sciences as key constituents of 'bioethics' all qualify as distinct elite cultures. During the period of my research, I have worked as a legal researcher with the Secretariat of the BAC. In this role, my primary responsibilities could be segregated into three main categories: conduct research into laws and regulatory policies of Singapore and select jurisdictions (aspects of which will be discussed in Chapters 3 to 5), produce analytical reports and facilitate the formulation of recommendations, and discharge general administrative duties, which include arranging and organizing meetings. I had four other colleagues: a medically trained head of the Secretariat, a psychology professor, a junior scientist (with a strong interest in STS), and an administrator. Whether working within the Secretariat or with the BAC (and its Working Group), we constantly endeavor to translate among, as well as associate, different knowledge systems. While these systems and the more specific scientific agenda are driven by public interests, their concerns reach far beyond day-to-day concerns of ordinary people. This

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50 Marilyn Strathern. Accountability…and ethnography. In Marilyn Strathern (ed), *Audit Cultures: Anthropological studies in accountability, ethics and the academy*. London: Routledge, 2000, pp 279-304, at 285.

51 Nikolas Rose, Pat O'Malley and Mariana Valverde, Governmentality. *Annual Review of Law and Social Sciences* (2006) 2:83-104, at 92.

52 Cris Shore. Introduction. In Stephen Nugent and Cris Shore, *Elite Cultures: Anthropological Perspectives.* London and New York: Routledge, 2002, at 9.

53 *Ibid*, at 6.

dissertation is hence a study of the 'high priests', and it attempts to provide some insights on: (a) the historical context by which elites can be meaningfully understood, (b) the external conditions and interests that promote and sustain local or national elites matched with the norms, values and shared interests that characterize or unite such elites, (c) strategies they use to reproduce themselves over time, and (d) the language and practices through which elites represent themselves and the techniques they use to legitimize their position.[54] I have focused on the 'high priests' largely because it was mainly at this level that 'bioethics' was being introduced and institutionalized in Singapore. As Annelise Riles explains, ethnography is especially suited for such a study, where actors are guarded.[55]

In this dissertation, I also attempt to provide an account of the relatively more anecdotal or social aspect of knowledge systems operating within bioethics. This "rather oblique form of knowledge practice" has been described by Douglas Holmes and George Marcus as having "a keen discursive character whereby information is endowed with social perspective and meaning".[56] The BAC members have intuitions and insights based on their observations, relationships and experience. However, such 'knowledge' does not count in 'serious' or 'academic' ethical analysis, even though it has been profoundly influential in steering the direction of bioethical policies. In attempting to represent this somewhat anecdotal bioethical knowledge, I provide an account of the "para-ethnographic"; or substantive, methodological and theoretical

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54 *Ibid*, at 12-13.

55 Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 13. Riles explains: "An anthropologist specializes in understanding what is so important, so fundamental, so much a part of the taken-for-granted agreed bases of social life that from the point of view of one's subjects it goes largely unnoticed. If the actor could simply tell you about the symbolic structures underlying their kinship, for example, you wouldn't need ethnography; you could simply conduct a telephone survey."

56 Douglas R. Holmes and George E. Marcus, Fast Capitalism: Para-Ethnography and the Rise of the Symbolic Analyst. In Melissa S. Fisher and Greg Downey (eds), *Frontiers of Capital: Ethnographic Reflections on the New Economy*. Durham and London: Duke University Press, 2006, pp 33-57, at 38.

considerations in the marginal ways of knowing within bioethics.[57]

I find reflexivity in ethnographic writing to be important as the conscious self-examination of the "interpretive nature of fieldwork, the construction of ethnographic authority, the interdependence of ethnographer and informant, and the involvement of the ethnographer's self in fieldwork."[58] It is employed to realize the overarching interests of ethnography in "meaning, interpretation, subjectivity, intersubjectivity, thick description, dialogics, and polyphony".[59] Arguably, reflexivity is a means by which to overcome the possible lack of distance between myself – the observer – and the observed. In view of my involvement in the work of the BAC, Pierre Bourdieu indicates that 'objectivity' may be compromised in that I would not be able to "objectify the objectifying distance and the social conditions that make it possible" to study the observed logic of practices.[60] George Marcus considers Bourdieu's view of 'objective' distance to be too restrictive. He argues that "Bourdieu's account is tone-deaf to the inevitable moments of subjective criticism that have always occurred in even the most scientific ethnography. By denying or ignoring this integral dimension of the most objectifying methods, Bourdieu misses

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57 Douglas R. Holmes and George E. Marcus, Cultures of Expertise and the Management of Globalization: Toward the Re-Functioning of Ethnography. In Aihwa Ong and Stephen J. Collier (eds), *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems*. Singapore: Blackwell Publishing, 2005, pp 235-252, at 240-241. As a methodology, they argue that para-ethnography is a means to re-functioning ethnography as "a way of dealing with contradiction, exception, facts that are fugitive, and that suggest a social realm not in alignment with the representations generated…Making ethnography from para-ethnography redefines the status of the subject or informant, asks what different accounts one wants from such key figures in the fieldwork process, and indeed questions what the ethnography of experts means within a broad, multi-sited design of research". *Ibid*, at 236-7.

58 Antonius C. G. M. Robben, Reflexive Ethnography. In Antonius C. G. M. Robben and Jeffrey A. Sluka (eds), *Ethnographic Fieldwork: An Anthropological Reader*. Singapore: Blackwell, 2007, pp.443-446 at 443.

59 *Ibid*, at 446.

60 Pierre Bourdieu. *The Logic of Practice*, trans. Richard Nice. Stanford CA: Stanford University Press, 1990, at 14. Bourdieu explains (at 26) that "[o]bjectivism, which sets out to establish objective regularities (structures, laws, systems of relationships, etc.) independent of individual consciousness and wills, introduces a radical discontinuity between theoretical knowledge and practical knowledge…"

the sorts of tensions that propel the ethnographer toward reflexivity in the first place..."[61] Associating Bourdieu's constrained reflexivity as sociological reflexivity, Marcus adds that there are other styles of less limiting reflexivity in anthropology and feminist scholarship. Anthropological reflexivity is "one that emphasizes the intertextual or diverse fields of representation that any contemporary project of ethnography enters and crosses in order to establish its own subject and to define its own voice."[62] Objectification through representation of the social phenomenon being studied as social facts depends not only on the discourse of the ethnographer, but also her literal position in relation to the subjects. The importance of positioning is given further emphasis in feminist reflexivity.[63] Donna Haraway's notion of 'situated knowledge' is helpful here.[64]

I worked collaboratively, and my sense is that this interactive engagement to ethnography is more equitable in that the ethnographer does *not* assume a more privilege position than her subjects. I am constantly aware that my account of bioethics, chimeras and hybrids is partial and hence not the last word on the subject. It also reflects ethnographic method as based on a "long-term commitment to research based on intensive and on-going relationships with informants, a mix of participant observation and open-ended interviews."[65] In addition, reflexivity is practiced both at the level of the BAC and also the Secretariat. Perhaps attributable to a number of conditions that include the reality and proximity of power relations, the indirect or tangential relevance of personal expertise of the BAC members and the Secretariat, and the evaluative

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61 George E. Marcus. *Ethnography Through Thick and Thin*. Princeton NJ: Princeton University Press, 1998, at 195.

62 *Ibid*, at 196.

63 *Ibid*, at 198.

64 Donna Haraway. *The Haraway Reader*. New York and London: Routledge, 2004, at 316-317.

65 Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 14.

nature of ethical work, reflexivity is encouraged in going "beyond calculative problem solving toward exploring tensions and recognizing the ephemeral nature of our identities and social experience…to question and explore how we contribute to the construction of social and organizational realities, how we relate with others, and how we construct our ways of being in the world."[66] In other words, neither BAC members nor the Secretariat could be conceptualized as purely rational creatures of expertise, but they have been "desiring, relating, doubting, anxious, contentious and affective".[67] This may also explain why learning in policy work, whether bioethics or not, could be metaphorically described as *bricolage*, and the policy-maker, a *bricoleur*.[68]

Another way by which I attempt to practice reflexivity is through speaking to people outside of the Secretariat and through writing. In relation to the former, the people whom I have interviewed include members of the BAC and HECR Working Group, policymakers, regulators and researchers. I have also conducted interviews – both formal and informal – with policymakers outside of Singapore. This aspect of my research serves to identify any sites of knowledge production that I might have missed. In 'unwinding' of my own position, I sought to determine new modes of relationship and expression.[69] To these, I add that ethnographic writing itself requires self-critical reflexivity,[70] and nondualism.[71] On this point, Marilyn Strathern

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66 Ann L. Cunliffe and Jong S. Jun, The Need for Reflexivity in Public Administration, *Administration & Society* (May 2005) 37, 2: 225-242, at 228.

67 Dominic Boyer, Thinking through the Anthropology of Experts, *Anthropology in Action* (2008) 15, 2: 38-46, at 38.

68 Richard Freeman, Epistemological Bricolage: How Practitioners Make Sense of Learning, *Administration & Society* (July 2007) 39, 4: 476-496.

69 Annelise Riles, Real time: Unwinding technocratic and anthropological knowledge. *American Ethnologist* (2004) 31, 3: 392-405.

70 Liisa H. Malkki, Tradition and Improvisation in Ethnographic Field Research. In Allaine Cerwonka and Liisa H. Malkki (eds), *Improvising Theory: Process and Temporality in Ethnographic Fieldwork*. Chicago: University of Chicago Press, 2007, pp 162-187, at 177.

provides instructive observation:[72] "Writing is much more…than the recording of facts and observations. Consequently, the ethnographer can no longer pretend to be a neutral vector for the conveying of information; her or his own participation in the constructed narrative must be made explicit." I find the experience of Brian Moeran to be helpful, and it reflects that 'front-stage' versus 'back-stage' differential in Stephen Hilgartner's work.[73] Drawing from his long-term fieldwork in a Japanese advertising agency, Moeran expresses reservation over the effectiveness of 'objective' fieldwork through participant observation and interviews, as "everyone knew who I was and could therefore approach or avoid me".[74] However, he was able to move from "front-stage impression management" to "back-stage" when he helped the agency win a multi-million dollar account from a prestigious Japanese electronics firm called Frontier. At that point, he was no longer regarded exclusively as a visiting foreign researcher.[75] Moeran had gained access to back-stage reality and discovered that what the organization actually does is very different from what its employees tell you. Given this, it is important for researchers to try to move from 'front-stage' to 'back-stage'. But in 'going native', he points out that one's 'objectivity' could be compromised for failing to achieve the required detachment for analytical purposes. For him, he states that returning to one's "home base" at an academic institution is a means of re-gain the analytical distance.[76] For my research, I started from the 'back-stage' of the organization. However, there is a constant awareness of the 'front-stage' when dealing with the press, at public

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71 Evens argues for "nondualism" in that although there is still an object-subject distinction, it is a relative rather than an absolute one. The ethnographic enterprise is observed to be "ontological to its very core". See Terry M.S. Evens. *Anthropology as Ethics: Nondualism and the Conduct of Sacrifice*. New York and Oxford: Berghahn Books, 2009, at 3.

72 Marilyn Strathern. *Partial Connections*. Savage ML: Rowman & Littlefield Publishers, 1991, at 7.

73 Stephen Hilgartner. *Science on Stage: Expert Advice as Public Drama*. Stanford: Stanford University Press, 2000. See especially Chapter 2.

74 Brian Moeran, From participant observation to observant participation. In Sierk Ybema, Dvora Yanow, Harry Wels and Frans Kamsteeg (eds), *Organizational Ethnography: Studying the Complexities of Everyday Life*. Chennai India: Sage Publications, 2009, pp. 137-155, at 153.

75 *Ibid* at 146-7.

76 *Ibid* at 154.

meetings and most certainly in preparing the reports of the BAC.

Lack of clear distance from my ethnographic subject(s) did result in a number of constraints, particularly in determining what to criticize and to what extent. In getting to know and understand the ideals, rationalities and idioms that my informants and research subjects live by, as well as in appreciating the many practical difficulties and uncertainties in 'hands-on' policy work, these constraints often present themselves as double binds in deciding what and how to represent ethnographically, and what is ethically responsible to critique.[77] Experiences of other ethnographers show that double binds are ubiquitous. Kim Furton describes a double bind situation in terms of its multiplicity and complexity of messages, their interrelations and reciprocal qualifications, which must be interpreted all at once. Hence, it creates persistent mismatch that forces us to 'dream up' new ways of understanding and engaging the world.[78] Her study of the Bhopal gas leak disaster in 1984 provides ample illustrations of situational double bind. The choice of a forum for litigation and a decision as to whether grassroots organizations should engage in legal battles represent two instances of double bind. On the former, there were as many reasons for the litigation to take place in the US as there were in India. Litigation in the US would serve to send a clear signal to multinational corporations (Union Carbide Corporation being the parent company of the fertilizer manufacturer in India) that they have responsibilities

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[77] As Anthony Wilden and Tim Wilson explained some time back, the phenomenon of 'double bind' is not simply a dilemma arising from a choice between two evils (of "damned if you do, and damned if you don't"). Rather, it requires a choice between two states which are equally valued. Anthony Wilden and Tim Wilson, "The Double Bind: Logic, Magic and Economics". In Carlos Sluzki and Donald Ransom (eds), *Double Bind: The Foundation of the Communicational Approach to the Family*. New York: Grune and Stratton, 1976, pp 263-86. As they define it (at 276): "A true double bind – or a situation set up or perceived as one – requires a choice between two states which are equally valued and so equally insufficient that a self-perpetuating oscillation is engendered by any act of choice between them…It is the fact that one must choose, and moreover choose between incompatible alternatives."

[78] Kim Fortun, *Advocacy after Bhopal: Environmentalism, Disaster, New Global Orders*. Chicago and London: University of Chicago Press, 2001, at 13.

vis-à-vis their foreign subsidiaries. The capability of the courts in India to adjudicate disputes that concerned its citizens was a message no less important, and one that litigation in India would effectively convey. On the latter, grassroots organizations has to decide whether to prioritize initiatives to build institutional structures for local decision-making or to engage in legal battles, give that "[t]he law can create a space for grassroots organizations to work, while undermining the very modes of sociality such space was to protect."[79] Andrea Timmer observes a similar double bind in the discursive strategies of European nongovernmental organizations (NGOs) that construct the Roma as problems that require attention. NGOs have to frame their activities in a manner that will encourage continued support from external government and funding agencies. However, the general standards prescribed as funding conditions could become an obstacle to the particular situational challenges that NGOs have to address.[80] In the context of law, Jacque Derrida has observed a double bind in the attempt to relate generality (such as a norm, rule or value) to particularity, especially in view of the possibility that the latter may be an outcome that is inconsistent with the former.[81] Derrida's critique finds clear application in much of the work of the BAC in having to relate particular biomedical expectations and practices to broader principles, so much so that it has not always been clear to me if the latter became more important than the research subjects and broader public whose interests the BAC has been tasked to safeguard. In addition, there was almost always an inherent conflict in having to choose between

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79 *Ibid*. Fortun identifies environmentalism as another double bind, as it relates to a political strategy that brings people together, but at the same time encompassed a "politics of fissure, rather than harmony" (at 16).

80 Andria D. Timmer, Constructing the "Needy Subject": NGO Discourses of Roma Need, *Political and Legal Anthropology Review* (November 2010) 33, 2: 264-281, at 267. For instance, funding was denied to an NGO because its work was not directed specifically at addressing the "Roma problem", but related to both Roma and non-Roma, as the main goal was to help integrate the former with the latter (at 268).

81 Jacques Derrida, Force of Law: The mystical foundation of authority. *Cardozo Law Review* (1990) 11: 920-1045, at 949 and 951. He observes: "To address oneself to the other in the language of the other is, it seems, the condition of all possible justice, but apparently, in all rigor, it is not only impossible…but even excluded by justice as law (*droit*), inasmuch as justice as right seems to imply an element of universality, the appeal to a third party who suspends the unilaterality or singularity of the idioms…It is unjust to judge someone who does not understand the language in which the law is inscribed or the judgment pronounced..."

promoting biomedical research and human subjects protection, where other considerations (especially those that relate to scientific knowledge as securing for the nation a competitive – often commercial – advantage) greatly confound earnest attempts at ethical valuation.

In discussing the life work of Gregory Bateson, his daughter Mary Catherine Bateson argues that as double bind is endemic in human life, it should not be perceived only as crippling (in creating psychopathologies for instance), but also occasions that provoke resolution or creativity.[82] Rather than think of double bind as a discrete thing or event, it is relational in its nature as "an abstract pattern of relationships that might show up in particular exchanges", and expression within a broader context.[83] Paradoxes and dilemmas that relationality creates are also opportunities to learn and grow. Bateson graphically illustrates this relationality as one that "we cannot leave and cannot do without, a relationship which must finally be one of love."[84] In review of Furton's work, Amy Levine observes that ethnography itself functions as a double bind.[85] Furton recognizes this throughout the course of her study.[86] In having to choose between different sources of data and orderings, the necessity of selective representation in ethnography precludes any claim to full mastery over one's data. Given the inevitability of exclusion (and informational loss), a key challenge has been to state as clearly as practicable the selection basis and its

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82 Mary Catherine Bateson, The Double Bind: Pathology and Creativity, *Cybernetics and Human Knowledge* (2005) 12, 1-2: 11-21, at 18-19.

83 *Ibid*, at 12.

84 *Ibid*, at 20.

85 Amy Levine, Book Review - Advocacy After Bhopal: Environmentalism, Disaster, New Global Order, *Political and Legal Anthropology Review* (2003) 26, 2: 171-175, at 174.

86 As Furton observes: "Competing demands would structure the work: Demands to acknowledge the unfigurability of disaster alongside demands for categorization…Demands to acknowledge both the contingent particularity of example and the universally valid…Demands for words that upheld entrenched regimes of power, alongside demands for words that disassemble…Demands to respect both past and future, embodied in the need to remember Bhopal so that we may forget, staging a future less determined by the force of repetition." Kim Fortun, *Advocacy after Bhopal: Environmentalism, Disaster, New Global Orders*. Chicago and London: University of Chicago Press, 2001, at 53.

consequences.[87] For this reason, an ethnographic work is always unsettled and open to ethical evaluation.[88] But if Bateson is right, the function of ethnography is more than a double bind. It could also serve as a nurturing response to the distressing challenges that one finds in the relationalities that one is embedded in. As Furton also recognizes, ethnography of double binds also creates a space for advocacy.[89] Like Derrida, Margaret Radin acknowledges that double bind is omnipresent in the pursuit of justice. However, she proposes active engagement, either in considering ways of changing the circumstances or to choose a regime for the meantime in addressing particular problems separately.[90] Ethnographic research inevitably has political implications.[91] I take June Nash's point that there is a risk of confusing representation of one's finding with advocacy, but this is arguably an inherent risk in all ethnographic works.[92]

As a legal scholar, my main distress in the field has been to confront the many 'myths' about the law that pervade the policy environment – that the law is slow to respond, legal requirements are unduly limiting, the law impedes scientific progress, etc. In working with the Secretariat, it has also been a dilemma in deciding the extent that the law needs to be presented on a formal basis. The ethnographic representations that I make are to a large degree a response to this distress, and

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87 *Ibid*, at 6.

88 *Ibid*, at 350: "An ethnography of Bhopal should not work toward final synthesis...The result can never be comprehensive. Expertise itself becomes a paradox, as does ethics. One is always confronted with more to understand and more to address than is possible. One must chose a focus, knowing that responding well to one problem ignores another…Asking questions about what is most valued won't work…But one must move, without fully understanding the complex systems in which one works. Ethics happen within such movement. Ethics play out in ways that cannot be controlled."

89 *Ibid*, at 175.

90 Margaret Jane Radin, *Contested Commodities*. Cambridge MA and London: Harvard University Press, 1996, at 122.

91 June C. Nash. *Practicing Ethnography in a Globalizing World*. New York: Alta Mira Press, 2007, at 29.

92 Marilyn Strathern indicates that reality should be grasped through a medium that already has a form of its own. In order to be true to human interlocution, the ethnographer must invite the reader to participate in what she or he participates, which is discourse. Rather than represent another society or culture, she or he should provide the reader with a connection to it: Marilyn Strathern, *Partial Connections*. Savage ML: Rowman & Littlefield Publishers, 1991, at 7 and 15.

to show what I regard as legitimate and indispensable contribution of law in policy work. More importantly, the critical standpoint that I adopt has been and remains relationally embedded, since criticism from a secure position of traditional ethnographic distance could understandably be regarded as arrogant and irrelevant. This relational viewpoint is further consistent with a rationale in pragmatism. Pragmatists argue that knowledge is contextual, social and inseparable from purposeful action. Ideas arise from experiences that are often encapsulated in social institutions.[93] In linking ethnography to pragmatism, Murray Leaf explains that there is no distinction in pragmatism between collecting data and analysis.[94] It follows from the situatedness of knowledge that it is unrealistic to believe that ethnographers can be a 'fly on the wall' in often antiseptic policy environments. Just as important is the nature of my ethnographic endeavor. It is not intended to be critical as its sole or even primary goal. But as Bateson indicates, ethnography is my attempt to depict opportunities to learn and grow.

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93 Alfonso Morales, Forward – Pragmatism as a Discipline: (Re)Introducing Pragmatist Philosophy to Law and Social Science. In Alfonso Morales (ed), *Renascent Pragmatism: Studies in Law and Social Science*. Cornwall: Ashgate Publishing, 2003, pp. xi-xxiv.

94 Murray J. Leaf, Ethnography and Pragmatism. In Alfonso Morales (ed.), *Renascent Pragmatism: Studies in Law and Social Science*. Cornwall: Ashgate Publishing, 2003, pp. 92-117, at 102. See also 99.

1.4 Organizations, Documents and Meetings

'Bioethics' as a policy discourse is embodied in, transmitted and shaped by the BAC. As such, an ethnographic study of 'bioethics' in Singapore is very much an ethnographic account of the BAC as an organization (or institution in an epistemological sense). In organizational ethnography, Sierk Ybema *et al.* provide a number of key features which I will adopt here as a framework for discussing my ethnographic study.[95]

Combined fieldwork methods are used in the form of participant observation, formal interviews and close reading of documentary sources. The close reading of documentary sources has been a critical aspect of my research. It is a means of recognizing the recurring linguistic and conceptual conventions and expectations. Mitchel Lasser's explanation in relation to the close reading of legal texts is instructive:[96]

> The basic idea is to approach the documents or arguments produced by a legal system as if they were serious literary works, and thus treat them with a similar degree of careful, detailed, and almost exhaustive attention. The underlying assumption, of course, is that these legal texts are meaningful in some way that transcends their already important substantive attributes…the methodology affirms that legal texts express an implicit conceptual universe that can fruitfully, if imperfectly, be made explicit by meticulous

[95] Sierk Ybema, Dvora Yanow, Harry Wels and Frans Kamsteeg, Studying everyday organizational life. In Sierk Ybema, Dvora Yanow, Harry Wels and Frans Kamsteeg (eds), *Organizational Ethnography: Studying the Complexities of Everyday Life*. Chennai India: Sage Publications, 2009, pp. 1-20, at 6-9. The seven key characteristics of interpretive organizational ethnography are listed as: (1) combined fieldwork methods, (2) at the scene, (3) hidden and harsh dimensions: power and emotions, (4) context-sensitive and actor-centered analysis, (5) meaning-making; (6) multivocality, and (7) reflexivity and positionality.

[96] Mitchel de S. –O. –L'E. Lasser. *Judicial Deliberations: A Comparative Analysis of Judicial Transparency and Legitimacy*. Oxford and New York: Oxford University Press, 2004, at 11-12.

literary analysis.

This ethnography is interested in registering the postmodern processes at work in everyday life – these postmodernist *'processes of pastiche'*. Pastiche allows for the thorough mixing of modes, meanings, styles. What remains rooted, or of momentary stability, are the processes and relations which connect locales, the sorts of factors, in other words, which shape pastiche, in any locale. It seeks to explore new ways of thinking about contemporary conditions.[97] In explaining the new legal realism, Sally Engle Merry associates this philosophy with methodologies that includes "transnational and multi-sited ethnographic research that tracks the flow of people, ideas, laws, and institutions across national boundaries and examines particular nodes and sites within this field of transnational circulation".[98] It is also accompanied by an expansion of the dimensions of legality to include "legal consciousness and emerging legal technologies that constructs and sediment forms of legal knowledge and practice".[99] Also noteworthy is her description of an approach to doing de-territorialized ethnography, by locating sites where global, national, and local processes are revealed in the social life of small groups.[100]

Christine Hine provides a further illustration of the multi-sited-ness of her study relating to the use of information and communication technologies (ICTs) in biological systematics, and exploring how these developments make sense to those involved in diverse situations.[101] These 'sites' include online discussion forums, museums, botanic gardens and herbaria, policy

97 George E. Marcus. *Ethnography Through Thick and Thin*. Princeton NJ: Princeton University Press, 1998, at 53-4.

98 Sally Engle Merry, New Legal Realism and the Ethnography of Transnational Law, *Law & Social Inquiry* (2006) 31, 4: 975-995, at 976

99 *Ibid*, at 980-982.

100 *Ibid*, at 981.

101 Christine Hine, Multi-sited Ethnography as Middle-Range Methodology for Contemporary STS. *Science, Technology, and Human Values* (2007) 32, 6: 652-671, at 666-7.

documents and web sites, journals, conferences, interviews, emails and informal conversations. This research is multi-sited in that she studied many different places to explore different aspects of a phenomenon.[102]

Like many other policy organizations, meetings and documents are essential characters of the BAC. Part of the work of the Secretariat entails the preparation of meetings and documents for a variety of purposes and audiences. The essential output of the BAC is recommendations published in the form of reports to the government on particular issues in the life sciences. In my research, I examine how certain documents such as comparative tables are important representations of institutional thinking and sense-making. Anthropologists have used documents to study the distinction between the 'text' and 'context'. For instance, in his ethnography of the International Monetary Fund, Harper shows the multiple relationships and meanings that texts conceal by looking at the different "careers" that the same document take.[103] Don Brenneis employs the term "career" of forms to illustrate how mundane forms in activities such as writing recommendations and evaluating research proposals constitute academic life in often subtle but concrete ways. As such, "career" may be seen as the very tangible effect that "artifacts" may have on macrocosmic phenomenon.[104] My recourse to documents is different from the studies of Harper and Brenneis. The production of reports on particular issues, such as egg donation and human-animal combinations, is the central preoccupation of the BAC. In that sense, it is analogous to a phenomenon that Annelise Riles refers to as: "Progress was internal to the document", so that the wider progressive scale of the BAC's endeavors does not rest in the larger

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102 *Ibid* at 668.

103 Richard Harper. *Inside the IMF: An Ethnography of Documents, Technology and Organizational Action*. London: Academic Press, 1998.

104 Don Brenneis. Performing Promise. In Annelise Riles (ed), *Documents: Artifacts of Modern Knowledge.* Ann Arbor: The University of Michigan Press, 2006, pp. 41-70, at 65.

progression of conferences and documents however, but in an emergent discourse on 'bioethics' both within and outside of Singapore.[105] In Chapters 2 to 5, I show the ways that documents mediate among different knowledge systems. Documents are thereby central to the movement of ideas. As Dorothy Smith argues, documents have a role similar to that of a tool or technology that enables certain kinds of association, abstraction and/or simplification.[106] Simplification is an essential character of writing policy documents,[107] but I agree with Thomas Yarrow that this does not necessarily imply evasion or disguise as certain 'erasures' are essential to enhance comprehension and facilitate dialogue.[108]

Unlike many other organizations, meetings are not as commonplace in the work of the BAC but they are important. Typically when a meeting is convened, there is an implicit understanding that either there is someone important to meet or there are important decisions to be made. During my time in the field, meetings have been convened to decide on various aspects of documents being prepared concerning issues in egg donation and/or human-animal combinations. As such, meetings are arguably 'tools' in the production of documents. More specifically, they are what Helen Schwartzman refers to as "communicative events".[109] In combination with documents (like the Beige Book and anecdotal reports used in the Open Market Committee meetings of the

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105 Annelise Riles. [Deadlines]: Removing the Brackets on Politics in Bureaucratic and Anthropological Analysis. In Annelise Riles (ed), *Documents: Artifacts of Modern Knowledge.* Ann Arbor: The University of Michigan Press, 2006, pp. 71-92, at 87.

106 Dorothy Smith. *Texts, Facts and Femininity: Exploring the Relations of Ruling*. London: Routledge, 1990.

107 Raymond Apthorpe, Writing Development Policy and Policy Analysis Plain or Clear: On Language, Genre and Power. In Cris Shore and S. Wright (eds), *Anthropology of Policy: Critical Perspectives on Governance and Power*. London: Routledge, 1997.

108 Thomas Yarrow, This is not the academic world of right and wrong: The obviation of truth through NGO documentary practice, *Cambridge Anthropology* (2006) 26: 50-59, at 57.

109 Helen B. Schwartzman, *Ethnography in Organizations*. Newbury Park CA: Sage Publications, 1993, at 39-40.

Federal Reserve Board),[110] meetings as communicative events give form and occasion to the para-ethnographic (discussed above).

1.5 Actor-Network-Theory

In *Science in Action*, Bruno Latour presents technology as, in essence, a 'black-box' constructed to secure the interests of a scientist and her or his enrolled allies, all of whom are intricately bound together by way of a network.[111] Within this network, we find the contributions of not only human agents but also non-human actants. The explicit purpose of this exercise is to sensitize our research to stronger and weaker heterogeneous associations.[112] More recently, he indicates that the way in which machines attribute roles and actions between humans and nonhumans may be understood by comparing machines with texts, since the inscription of builders and users in a mechanism is very much the same as that of authors and readers in a story.[113] In the design of a machine, engineers attempt to confine users within a particular frame or script through a process that Latour refers to as inscription, translation or delegation. The intended behavior can be imposed on human users by nonhuman delegates through prescription, which is the moral and ethical dimension of the mechanism. The result is that the sum of

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110 Douglas R. Holmes and George E. Marcus, Fast Capitalism: Para-Ethnography and the Rise of the Symbolic Analyst. In Melissa S. Fisher and Greg Downey (eds), *Frontiers of Capital: Ethnographic Reflections on the New Economy*. Durham and London: Duke University Press, 2006, pp 33-57, at 37-8.

111 Bruno Latour. *Science in Action: How to Follow Scientists and Engineers through Society*. Cambridge MA: Harvard University Press, 1987, at 130-133. At its best, technology such as the thermometer becomes an "obligatory point of passage" that defies dissent to its prescriptions.

112 *Ibid*, at 127 and 240.

113 Bruno Latour, Where are the Missing Masses? The Sociology of a Few Mundane Artifacts. In Wiebe Bijker and John Law (eds), *Shaping technology/Building Society: Studies in Sociotechnical. Change* Cambridge MA: MIT Press, 1992, pp 225-259, at 236.

morality (prescribed by nonhuman delegates) increases enormously with the population of nonhumans.[114]

Two features of Latour's Actor-Network-Theory (ANT) are especially pertinent to my research. The first is anti-essentialism, particularly in not differentiating between science (as knowledge) and technology (as artifact), or to otherwise privilege science over other knowledge practices. Second, ANT advances a relational materiality, which postulates that all entities achieve significance in relation to others, thereby by-passing the distinction between agency and structure.[115] Rather than personify things, Latour's endeavor to denaturalize voice and give emphasis to mediation is helpful, and a point that we will return to consider in Chapter 6.[116] In this research, I apply the ANT/STS methodology more generally, and in a manner that Mariana Valverde, Ron Levi and Dawn Moore explain as:[117] "In keeping with ANT/STS methodology, our approach treats all uses and deployments of knowledge claims as equal, without making judgments about who should or should not be making these claims." Following Michel Foucault and Bruno Latour, they argue that "knowledges do not belong to anyone or to any site. Knowledges are always circulating, changing, being taken apart, and reassembled in new shapes by new actors."[118] As an exemplar, Annelise Riles has applied ANT to analyze human rights activism in Fiji. She shows that by studying specific textual technique of bracketing phrases on which there have been no general agreement, these brackets have become an actor in their own

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114 *Ibid*, at 247.

115 An account of the dehumanization of agency is provided by Kapil Raj. Kapil Raj, When human travellers become instruments: The Indo-British exploration of Central Asia in the nineteenth century. In Marie-Noëlle Bourguet, Christian Licoppe and H. Otto Sibum (eds), *Instruments, Travel and Science: Itineraries of precision from the seventeenth to the twentieth century*. London and New York: Routledge, 2002, pp. 156-188.

116 Bruno Latour (translated by Catherine Porter), *Politics of Nature: How to Bring the Sciences into Democracy*. Cambridge MA: Harvard University Press, 2004, at 68.

117 Mariana Valverde, Ron Levi and Dawn Moore, Legal Knowledges of Risk. In Law Commission of Canada, *Law and Risk*. Vancouver and Toronto: University of British Columbia Press, 2005, pp 86-120, at 89.

118 *Ibid*.

right, particularly in enabling a document on women's right to be crafted.[119] As Ron Levi and Mariana Valverde make clear:[120] "Riles's point is *not* that the women do not have agency, but that if we only ask about agency, structure, and material resources, using conventional social science, we will miss seeing things that actually made a crucial difference in real life, such as, in this case, the little technology for governing people, words, and laws that is the UN parenthesis." Returning to the subject of ethnography, Christine Hine similarly observes that due perhaps to the displacement of human agency, "[a]ctor network theory has often not been overtly ethnographic, nor indeed has it dwelt particularly on any links with methodological traditions from social science or anthropology."[121] Instead, STS scholars have innovatively developed ethnographic approaches so that the locality of science itself not only becomes a matter for study, but is widened beyond the laboratory to include social and cultural phenomena in multiple localities.[122]

My choice of Latour's ANT was largely influenced by a growing sense that 'law' could not be neatly separated from the other knowledge fields, such as 'science', 'politics' and especially 'ethics' in my research into the establishment of a governance structure for human embryonic stem cell research. More importantly, ANT does not regard the 'social' as a thing, but as "many

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119 Annelise Riles, *The Network Inside Out*. Ann Arber: University of Michigan Press, 2001.

120 Ron Levi and Mariana Valverde, Studying Law by Association: Bruno Latour Goes to the Conseil d'État, *Law & Social Inquiry* (2008) 33, 3: 805-825, at 812.

121 Christine Hine, Multi-sited Ethnography as Middle-Range Methodology for Contemporary STS. *Science, Technology, and Human Values* (2007) 32, 6: 652-671, at 660.

122 Attila Bruni, Shadowing software and clinical records: On the ethnography of non-humans and heterogeneous contexts. *Organization* (2005) 12, 3: 357-378; John Law, *After method: Mess in social science research*. London: Routledge, 2004; David J. Hess, Ethnography and the development of science and technology studies. In Paul Atkinson, Amanda Coffey, Sara Delamont, John Lofland, and Lyn Lofland (eds), *Sage handbook of ethnography*, pp. 234-245. Thousand Oaks, CA: Sage, 2001.

connecting elements circulating inside tiny conduits."[123] In his study of the production of legal knowledge, Latour gives emphasis to "law as a way of arranging the social world rather than as a field that is produced through external social causes", principally by treating "law as a network of people and of things in which legality is not a field to be studied independently, but is instead a way in which the world is assembled, as attribute that is attached to events, people, documents, and other objects when they become part of the decision-making process in the Conseil d'État."[124] By focusing on the details relating to the progression of legal cases through the French Supreme Court of Appeal for cases on administrative law, 'law' is made through chains of networks and translations involving texts, people, architecture, concepts and office objects – none of which are completely 'internal' or 'external' to the phenomenon of 'law'.[125] Latour describes 'law' as a hybrid or "factish", involving both material and ideological elements that cannot be entirely separated or purified.[126] Legality is to be understood in turn by the relations among its constituting documents and other entities.[127] In other words, Latour regards legal decision-making as critically the *mediation* of associations between a dossier of documents (which could include death certificates, receipts, reports of eyewitnesses) with library documents (such as statutes or past decisions). As Levi and Valverde explains, Latour's account of law is associational and mediatory, in that it is a "documentary network" and is concerned with

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123 Bruno Latour, *Reassembling the Social: An Introduction to Actor-Network-Theory*. Oxford: Oxford University Press, 2007, at 5. More importantly, ANT "claims that it is possible to trace more sturdy relations and discover more revealing patterns by finding a way to register the links between unstable and shifting frames of reference rather than by trying to keep one frame stable". *Ibid*, at 24.

124 Ron Levi and Mariana Valverde, Studying Law by Association: Bruno Latour Goes to the Conseil d'État, *Law & Social Inquiry* (2008) 33, 3: 805-825, at 806.

125 Bruno Latour, *La fabrique du driot: Une ethnographie du conseil d'État* [The factory of law: an ethnography of the Conseil d' d'État]. Paris: La Découverte, 2002, at 79-81 and 103 to 104. See discussion by Levi and Valverde: *Ibid*, at 813-4.

126 Latour: *Ibid*, at 297.

127 *Ibid*, at 88-89.

"import-export…[and] seeks to stitch together bits of the outside world with the network of files".[128]

A critical contribution from Latour's works is his emphasis that scientists as well as lawyers represent, through a variety of means that include staging or mediation, which has a distinctive agency. Lisa Disch observes that in amalgamating 'fact' (fait) and 'fetish' (fétiche) in the term "faitiche", Latour attempts to highlight that "agency is not localized in any particular agent but that materializes when an activity that engages actors in an exchange of properties produces something that "overtakes" them".[129] In defining an experiment as a 'movement' of three distinct trials that entail a story, a situation (composed of apparatuses that isolate the properties of the entity and stage it) and a trial of peers, Latour is said to have presented an autoethnography of the laboratory; or a means to "talk about agency that is not seated in a subject but rather distributed throughout a system of representation or a field of action".[130] A successful experiment is thereby also an indexical sign that is generative of ontological and epistemological content and encompasses representations that are political, symbolic and juridical all at once.[131]

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128 Ron Levi and Mariana Valverde, Studying Law by Association: Bruno Latour Goes to the Conseil d'État, *Law & Social Inquiry* (2008) 33, 3: 805-825, at 818-819 (Emphasis in original). Levi and Valverde describe the Latourian approach as "a study of practice and of assemblage" that is "deeply empiricist, seeking to demonstrate the wide range of human and nonhuman actors required for law to remain in place" (at 822). For the purposes of this research, an important feature of the approach is that it enables the mentalities and rationalities of government as articulated in statutes, cases and briefs to be included, along with the wide range of nonhuman actants: *Ibid*.

129 Lisa Disch, Faitiche-izing the People: What Representative Democracy Might Learn from Science Studies. In Bruce Braun and Sarah J. Whatmore (eds), *Political Matter: Technoscience, Democracy, and Public Life*. Minneapolis and London: University of Minnesota Press, 2010, pp 267-296, at 275. Disch adds that (*Ibid*; Emphasis in original): "Latour goes out of his way to define *faitiche* as a kind of movement or exchange – a passage or passing – rather than as a kind of thing…autonomy is not a localized capacity but a distributed agency that comes from the exchange of properties among an author, an apparatus, and a phenomenon."

130 *Ibid*, at 281.

131 Ibid, at 282-283. Latour explains an experiment is "a text about a nontextual situation, later tested by others to decide whether or not it is simply a text. If the final trial is successful, then *it* is not just a text, there is indeed a real situation behind it, and both the actor and its authors are endowed with a new competence." In other words, the successful replication of an experimental outcome renders the experimental apparatuses as "reliable witnesses" and the scientist as a legitimate spokesperson for the experimented phenomenon. See Bruno Latour,

1.6 Dissertation Overview

In Chapter 2 that follows, we consider the juridification of *generic* nascent life, by studying the way in which the BAC constructed human-animal combinations as regulatory objects (and subjects). It is argued that the techniques of categorization, systematization, distantiation and objectification have been deployed in the process. In categorization, the BAC first grouped together the different types of human-animal combinations that can be purposefully created by scientists. Following this, it systematically selected two main types of combinations – animal chimeras and cytoplasmic hybrids – to direct its attention to. Mainly through a documentary process, these biological constructs are then objectified, and distantiation is achieved mainly through the ritual of public consultation. Application-wise, these objects could be regarded as metaphorical models of 'Seeing-As' that are created to displace their more commonly perceived equivalents in folk knowledge. However, I go further to argue that chimeras and hybrids should more accurately be understood as placeholders, or metaphorical models of 'Seeing As-If'. This reference better represents the temporal and 'open texture' qualities of these constructs, particularly since both chimeras and hybrids are neither strictly 'human' nor 'non-human' in legal epistemology. Nevertheless, it is important to recognize that these constructs are not only biological, but also regulatory subjects. The political significance of this is that chimeras and hybrids could then fall under regulatory control, thereby enabling research to proceed on a 'regulated' basis. For the purposes of this study, the regulatory nature of chimeras and hybrids suggests that the techniques deployed have legal character and/or content.

Pandora's Hope: Essays on the Reality of Science Studies. Cambridge MA and London: Harvard University Press, 1999, at 123-124.

As placeholders are sustained within one or more 'scripts', we examine the BAC's 'script' and scripting process in Chapter 3. This study makes a number of findings. First, the 'script' has been profoundly influenced by the scripting process.[132] Scripting occurred across different 'scripts' and on a global scale. It is argued that the character of the 'script' is broadly defined by particular 'focal points' that serve as linkages. In theory, this provides a relatively novel account of 'legal globalization' that occurs in a policy environment. Second, documents have been found to play a crucial role in the forming of linkages. They functioned in essence as 'script-carriers'. Taking these two findings together, this research demonstrates the importance of close reading of text and multi-sited analysis as methodologies (we discuss this aspect further below). Third, the script possesses a limited anthropological content, which is both relational and normative. Chapter 4 builds on this aspect on the script, by focusing on comparison as technocratic practice and self-knowledge.

Whether as a field of academic study or as a matter of practical application, bioethics is not represented by a single goal, intellectual tradition, methodology or epistemological orientation.[133] Yet comparison is almost taken-for-granted in analyses within these cultural and disciplinary constituents. Thus, for instance, comparative law (and regulation) is relatively commonplace in the public bioethics genre. Consequently, comparison has generally assumed a legal character, operating largely on the implicit assumption of law or legal discourse as a constituent of, or contributor to, the epistemology of bioethics. To the extent that comparative law is a constituent of bioethics, legal issues similarly attend to comparisons in bioethics.

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[132] My use of the term 'script' is inspired by Latour's ANT, where networks confer qualities and instill motivations to actors through establishing roles as scripts. The process of scripting relates more generally to 'translation' in ANT although I hesitate to use this term as the outcome need not necessarily result in inscriptions or immutable mobiles.

[133] Renee Fox and Judith P. Swazey, *Observing Bioethics*. New York: Oxford University Press, 2008, at 9.

Interestingly, given that a bioethical inquiry could already have a particular ethical framing or lineage, it may be necessary to consider if the comparison is merely justificatory rather than investigative and/or constructive. In other words, a question to consider is whether the comparison is 'real' in its suggestion of similarities and/or differences. I argue that comparison could be both investigative and constructive, thus blurring the distinction between technique and epistemology.

In Chapter 5, I shift focus from process to rationale, by considering risk as a motivation behind juridification. In particular, I argue that risk is an anticipatory civic epistemology that arises from the script. This in turn necessitates precaution, its corollary, as a meta-legal principle and a technology of preparedness. As to the nature of risk, literature mainly points to the Weberian notion of risk as rationalization within an institutionalized space. As civic epistemology however, I argue that risk (and precaution) has a more pluralistic identity, and could be regarded as arising from a 'common fund of knowledges'. To be sure, I proffer this pluralistic account for unquantifiable or 'ethical' risk. At least in bioethics, quantifiable risks continue to be addressed within an often highly institutionalized framework. As to the social dynamics of risk, the finding from my research is relatively ambiguous in that it could be both individualizing and unifying. If risk is conceptualized as anticipatory civic epistemology and deployed as a political technology of preparedness, it appears to have a greater unifying quality. Arguably, risk has become a meta-network with a high level of convergence, in that it is both highly aligned and coordinated. This phenomenon could in turn provide a broad rationale for juridification.

In the final Chapter of this dissertation, I provide an account of juridification as the contribution of legal rationalities, norms, techniques and practices in co-producing and sustaining epistemic claims and artefacts (ie chimeras and hybrids) within the governmentality of biomedical research. Reflecting on the works of Foucault, my research suggests a broader reading of law in governmentality in at least two ways. First, law should be understood as comprising juridical institutions, norms and rationalities (as encapsulated in a variety of forms). Second, conceptualization of the relationship between law and disciplinary (and bio-) powers should be more dynamic. This reading provides a richer account, not only of the relationship between law and disciplinary powers (eg science), but also of governmentality as a power-complex. I argue that ANT is especially appropriate as a mode of inquiry that explicates particular network configurations of power modalities and the 'space' within which they are sustained within this power-complex. This analytic is referred to as regulationism. When applied to the BAC as my key ethnographic subject, I argue that law remains central to our experience of modernity.

On this note, we now proceed to consider our *objet trouvé* – chimeras and hybrids.

CHAPTER 2

CHIMERAS AND HYBRIDS AS REGULATORY PLACEHOLDERS

Abstract

In a policy environment, ‘placeholders’ are relatively commonplace (but understudied) devices that enable communication and policy development across possibly irreconcilable differences. The construction of these devices has been achieved essentially through the deployment of legal techniques of categorization, systematization, distantiation and objectification. This research shows how hybrids and chimeras have been constructed by the BAC as metaphorical placeholders. At one level, they are metaphorical for being ‘world conceiving’ or as models of ‘Seeing As’. It is argued that they are more accurately placeholders or models of ‘Seeing As-If’ given their temporal and ‘open texture’ qualities. Although tentative in meaning, placeholders are useful as ‘pockets’ of resources that enables more immediate policy objectives to be met; in this case, the regulatory governance of organisms that are neither ‘human’ nor ‘animal’. In studying the operation of these legal techniques, the research explicates: (1) the rationales and processes entailed in a form of legal objectification; and (2) a broader ‘placeholding’ capability of legal norms and techniques in weaving together different discourses – primarily ethics, medicine and science – in a manner (arguably inclusive of discursive interactions) that enables purposeful public action through regulation.

2.1 Introduction

I learnt of Dr. Irving Weissman's proposed creation of a mouse with a human brain when assisting in research that would culminate in the SC Report. That was in 2001. But as the proposal – however interesting – was not an issue of immediate interest or relevance at that time, the matter was put aside only to be taken up again some years later. By 2007, the institutional framework developed for hESC research conferred on his work a sense of place and a sensibility of purpose. Weissman proposed to create a mouse with a brain composed of human-derived neurons within a structure of mouse glial cells. This could be done in a number of ways; one of which was through transplanting human brain stem cells into an inbred strain of an immunologically deficit (called severe combined immune deficiency or 'SCID') fetal mouse just before the degeneration of its own brain cells. The objective of the research was to study human neurons *in vivo* in a laboratory animal.[134] An earlier experiment involving the introduction of human brain stem cells into a fully functioning brain of a mouse showed the former behaving like murine brain cells. So if a mouse could be created to possess only human brain cell but functioning within a murine brain structure, the outcome might allow something to be said about whether there is anything 'human' about the brain cells, and more generally, about characteristics that are essentially 'human'. Although the experiment was approved by Stanford University's IRB, the research was not carried out due possibly to the (scientific) difficulty in determining if the firing of human-derived neurons in a mouse could be said to be the same as their counterparts in a human being.[135] Still, this episode is important for a number of reasons. First, it is an indication of a scientific rationality and trajectory. Second, it marks the beginning

[134] Henry T. Greely, Mildred K. Cho, Linda F. Hogle and Debra M. Satz, Thinking About the Human Neuron Mouse. *The American Journal of Bioethics* (2007) 7, 5: 27-40, at 31.

[135] *Ibid*.

of formal (or institutional) deliberation on chimeras and hybrids. Third, it triggers critical reflection on what we know about these constructs and how much more is to be known. It further raises questions on what should be regarded as 'human' characteristics. As we shall see, these questions will require (albeit tentative) regulatory responses if the research is to have meaning beyond the realm of science.

Chimeras and hybrids are creatures of human design and exist only in the sanitized confines of the laboratory. With very limited exceptions, they do not differ significantly in form from their counterparts in the natural environment. In the usual course of life, ordinary people are unlikely to come into contact with these wondrous creatures. Indeed, most people will not in the course of their lives. But chimeras and hybrids also exist in human imagination, in myths and, to some degree, in day-to-day language under the more generic expression of 'monsters'. They are metaphors made vivid in Michael Crichton's *Next*.[136] We see them even in discussions of contemporary affairs. Niall Fersuson's 'Chimerica' depicts the negative consequence of combining Chinese surplus and American deficit as having contributed to the most severe credit crisis since the Great Depression.[137] When it became clear that chimeras and hybrids are to be deliberated upon by the BAC, the feeling at the Secretariat was both of excitement and concern. Chimeras and hybrids are material constructs at the forefront – not only of science, but also of ethics, law and the social sciences as these various disciplines attempt to make sense of this development. As metaphors however, the negative connotations present an almost implacable obstacle to any meaningful discussion. More daunting was the complexity and breadth of the subject matter. As a lawyer, my initially reaction was an unsettling excitement. Legal training in

136 Michael Crichton. *Next*. New York: HarperCollins Publishers, 2006.

137 Niall Ferguson. *The Ascent of Money: A Financial History of the World*. New York: Penguin Books, 2008, at 333-341.

matching social phenomena to legal paradigms did not at first seem relevant. The purpose was not to constitute chimeras and hybrids as legal 'subjects' in a strict sense – not immediately at least. Furthermore, the law has in almost all cases clearly distinguished between humans and nonhuman animals. The chimeras and hybrids that we are to deal with have components of both. Even if these constructs did fit into an existing legal category, what are the rules that should apply? And to whom? My colleagues and I also expected the public to be interested, grave and possibly adverse. Perhaps in anticipation of this, the SCLS advised a systematic and cautious approach. Consequently, the consultation paper on the subject was less directive than previous consultation papers, and no recommendations or guidelines were proposed for consideration. Shortly after the commencement of public consultation, I met a faculty member along a corridor that linked the Faculty of Law to the Lee Kuan Yew School of Public Policy at the Bukit Timah campus of NUS. Trained as an engineer and a lawyer at London and Oxford, he commented that lawyers are not generally accustomed to such open-endedness in consultation documents. In what sounds to me like Lon Fuller,[138] he added that there would be little that the Law Reform Committee of the Singapore Academy of Law (of which he was a member) could provide by way of feedback given the absence of legal rules on the subject.

Ironically, it was the legal and ethical techniques of categorization, systematization, distantiation and objectification that gave form to chimeras and hybrids. Ethical and legal analytics and techniques have played a vital role in a number of ways. First, it discredited existing models *of* chimeras and hybrids. Second, it co-constructed a model *for* these biological constructs through a process of categorization. This construction was based on science and ethics but through a

[138] Lon L. Fuller. *The Morality of Law*. New Haven: Yale University Press, 1969. Fuller indicates (at 47) that an 'internal morality of law' is that there must be rules. These rules need not be in the nature of legislation and would include those promulgated by administrative agencies (at 168-173).

process akin to legal adjudication. My field experience suggests a direct contribution of legal knowledge and technique in the making of chimeras and hybrids in the BAC's documents. But why create these categories? One reason is that the substitution of old (or more conventional) meanings embedded in the metaphors for new enables discussion, especially in public forums. Another reason just as important is that ethical and legal categories create regulatory objects. By definition, regulatory objects can be controlled through means of ethical values and 'law'. This in turn gives meaning to regulatory risk and further enables a response to certain modes of arguments, such as a concern with descent down the 'slippery slope'. Hence the third reason ethics and law have been important in the policy process relating to chimeras and hybrids is that it is not only anticipatory; it realizes what Annelise Riles refers to as 'as if' legal fictions or placeholders.[139] This way, it pre-empted public reaction and thereby stabilized what could have been a volatile discursive terrain. The deployment of ethical and legal knowledge in sustaining certain distinctions, such as the great chasm that has been built between humans and nonhuman animals is illustrative. But there are also limitations to categorization through objectification. In a policy environment, a danger lies in the treatment of these 'objects' as truisms.

Drawing on Annelise Riles's analysis of legal techniques in a variety of forms, this Chapter provides an account of the application of ethical and legal techniques within bureaucratic and public environments. Broadly speaking, these techniques are regulatory and entail styles of argumentation and systematic reasoning. We focus in particular on the use of these techniques in constructing metaphors as conceptual models, which is another major theme of this Chapter. It is argued that the metaphorical construction of 'hybrids' and 'chimeras' as models of 'Seeing As-

[139] Annelise Riles. Collateral Expertise: Legal Knowledge in the Global Financial Markets. *Current Anthropology* (2010) 51, 6: 795-818, at 802-803, and 815. See also Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 172-175.

if' enables regulatory control. Referring to the works of Lakoff and Johnston on metaphors, James Underhill identifies fundamental claims in metaphors as influencing the way people formulate ideas and express them (eg 'time is money'), form systematic constructs (eg refusing to 'waste' one's time in a 'profitless venture'), highlight and hide (eg 'Argument is War' conceals the fact that it can also be constructive), contradict one another (especially since conceptual metaphors can be mutually exclusive), grounded in experience that corresponds with one's experience of reality (eg 'Ideas are Food'), create similarity (eg 'The Stock Market is up today' where 'More is Up'), and widen cardinal trope to embrace other forms of comparison (eg 'pretty as a rose').[140] While the 'hybrids' and 'chimeras' in the BAC's documents may be more limited in discursive substance and temporality relative to the metaphors that Underhill considers, they have been effectively deployed as placeholders. In the context of this study, the metaphorical effectiveness of 'hybrids' and 'chimeras' as regulatory devices has been dependent on their capability to be applied as placeholders. The construction of these placeholders has not been limited to Singapore, but involved iterative interactions across several jurisdictions. These interactions will be considered in Chapter 3, followed by a discussion of the application of comparative methodologies entailed, in Chapter 4. We begin by considering how these metaphorical forms are reconstituted by the BAC.

[140] James W. Underhill. *Creating Worldviews: Metaphor, Ideology and Language*. Edinburgh: Edinburg University Press, 2011, at 25-29.

2.2 Defining Human-Animal Combinations in Singapore

Almost immediately following the publication by the BAC of its recommendations on egg donation for stem cell research on 7 November 2007,[141] a consultation paper (HA Consultation Paper) on the creation of cytoplasmic hybrid embryos and chimeric animals (under the broader rubric of human-animal combination) was released to the public on 8 January 2008.[142] The overall format of the HA Consultation Paper did not differ substantially from earlier consultation papers prepared by the BAC in that there was relatively clear segmentation of discussion relating to the scientific, ethical and legal implications of the subjects. But unlike its predecessors, the HA Consultation Paper did not propose any recommendation for consideration. The overall tone of the Consultation Paper was task oriented, and hence pragmatic. In devising a definition for chimeras and hybrids, it did not attempt to explain the essence of 'humanity'. Instead, the focus fell on the types of human-animal combinations that were already used in research or in facilitating medical therapy and those that researchers have a prospective interest in developing. The action-orientation of policy documents required the outlay of information to be made in a way that can direct meaningful responses to policy challenges. As an interest was in exploring the possibility of using animal eggs for SCNT, the creation of a cytoplasmic hybrid embryo was further elaborated on in the draft consultation paper. It was schematically represented as:[143]

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141 Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, 3 November 2008.

142 Bioethics Advisory Committee, Singapore, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*, 8 January 2008.

143 Fieldnotes, 27 July 2007: Draft Consultation Paper, at 4.

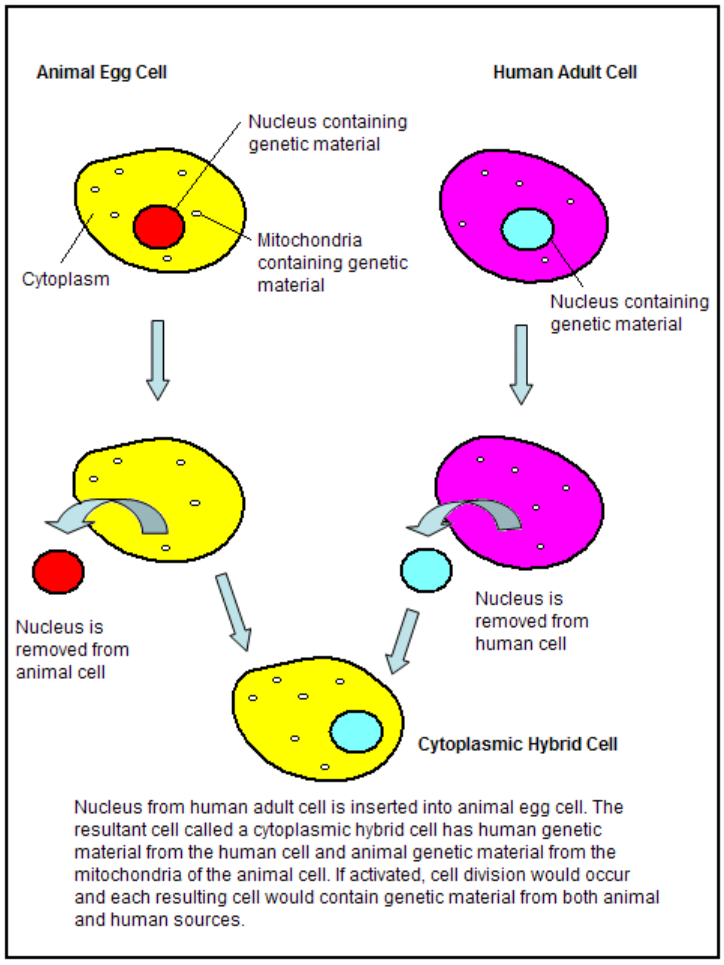

Figure 1. Creating a Cytoplasmic Hybrid Embryo

In fact, prior to the release of the HA Consultation Paper, human-animal combination was already a moot topic in the public domain. For instance, a commentary specifically on the subject was published in the mainstream local Chinese newspaper on 1 July 2007.[144] The commentary was entitled '人面兽身', which suggests a tendency for a lay person to associate research involving human-animal combinations with the creation of monsters.[145] In Chinese culture,

144 Fieldnotes, 21 August 2008.

145 陈华彪, 人面兽身, 联合早报 [Chen HB. Human Face Beast Body, Combined Morning Paper], 1 July 2007.

unions between man and beast tend to have very bad connotations.[146] However, the newspaper commentator – a biology graduate student – indicated that most people he knew did not object to the research after the objectives and nature of these scientific constructs were clearly explained to them.

Clarity in defining 'human-animal combinations' was necessary in drafting the HA Consultation Paper. Purely from the standpoint of scientific capability, a broad spectrum of human-animal combinations can be produced through some combination of cells and/or genetic materials. However, the consequences of the mixing are less clear. For instance, it is not known if a mouse that has a brain composed entirely of human neural cells would exhibit characteristics that one could recognize as 'human'. Even then, there are good reasons to expect that a primate (being 'closer' to human beings in evolutionary terms) is more likely to exhibit 'human' characteristics if its brain (being structurally similar to that of a human) was composed entirely of human neurons than would a mouse. In addition, the developmental stage of the research entity (be it an embryo or a fully developed organism) is relevant as this may have an effect on the extent of integration between host tissues and the introduced cells or genetic materials. Hence, despite the uncertainties, useful analytical measures have been identified as including the extensiveness of the human-animal mix, the type of organism concerned, and the developmental stage of this organism. A general taxonomy comprising three main types of human-animal combination, being chimeras, hybrids and transgenic organisms,[147] was devised after a relatively detailed

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146 Interview with sociologist and BAC member, Professor Eddie Kuo, 28 April 2009.

147 In the HA Consultation Paper, a chimera is defined as an "organism whose body contains cells from another organism of the same or a different species", whereas a hybrid is an "organism whose cells contain genetic material from organisms of different species." A transgenic animal is an "animal that has a genome containing genes from another species". See Bioethics Advisory Committee, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 8 January 2008, pp 40-42.

review of scientific, ethical, legal and policy literatures on the subject. Table 1 sets out the possibilities categorically.[148]

Table 2. Types of Human-Animal Combination

Type of human-animal combination	Definition Embryo	Definition Developed entity	Examples of uses in research
Human chimera (with some animal cellular material)	An embryo created by introducing one or more animal cells, usually stem cells, into a human embryo at an early stage of development. Any particular cell from the resulting embryo could be traced back either to the human or animal source.	An entity brought to term from a preponderantly human chimeric embryo. Animal cells would be present in many or all of its tissues. This entity may also be created by introducing animal cells into a person or into a human embryo at a later stage of development. Such an entity would have animal cells present only in a few tissues.	No known proposals to create such chimeric embryos or entities for research purposes (other than for clinical transplant research).
Animal chimera (with some human cellular material)	An embryo created by introducing one or more human cells, usually stem cells, into an animal embryo at an early stage of development. Any particular cell from the resulting embryo could be traced back either to the human or animal source.	An entity brought to term from a preponderantly animal chimeric embryo. Human cells would be present in many or all of its tissues. This entity may also be created by introducing human cells into an animal or into an animal embryo at a later stage of development. Such an entity would have human cells present only in a few tissues.	Growing human organs in animals for the purpose of transplantation into humans. For testing the pluripotence of stem cells, for example, via the transplantation of such cells into immuno-deficient mice. To evaluate the potential usefulness and safety of transplanting human stem cells for clinical treatment, by testing such stem cells in animals. For creating disease-specific research models such as the HIV infected SCID-Hu mouse.

[148] Important sources of information for this table include documents of the US National Academy of Sciences and the UK Academy of Medical Sciences. See The National Academy of Sciences, USA, *Guidelines for Human Embryonic Stem Cell Research*, 2005 (amended 2007 and 2008); and The Academy of Medical Sciences, *Inter-species embryos: A report by the Academy of Medical Sciences.* London: Academy of Medical Sciences, June 2007.

Table 2 (Continued)

Type of human-animal combination	Definition Embryo	Definition Developed entity	Examples of uses in research
Human-animal cytoplasmic hybrid or cybrid (with a human nuclear genome)	An embryo created by replacing the nucleus of an animal egg with the nucleus of an adult human somatic cell.	An entity brought to term from a human-animal cytoplasmic hybrid embryo with a human nuclear genome.	The embryo may be used for studying the processes involved in nuclear reprogramming, which may lead to deriving patient-specific stem cell lines. May also potentially be used to derive disease-specific stem cell lines for the purpose of research on specific diseases. No known proposals to bring a human-animal cytoplasmic hybrid embryo to term for research purposes.
Animal-human cytoplasmic hybrid (with an animal nuclear genome)	An embryo created by replacing the nucleus of a human egg with the nucleus of an adult animal somatic cell.	An entity brought to term from a human-animal cytoplasmic hybrid embryo with an animal nuclear genome.	No known proposals to create animal-human cytoplasmic hybrid embryos or entities for research.
True human-animal hybrid	An embryo created by fertilising an animal egg with a human sperm or *vice versa*. Any particular cell from the resulting embryo contains almost equal genetic contributions from both human and animal source.	An entity developed from a human-animal true hybrid embryo.	Not used in research, although the human-animal true hybrid embryo has been used to assess or diagnosis sub-fertility.
Transgenic human (with some animal genetic material)	A human embryo with animal genes inserted.	A human being developed from a human embryo that has integrated animal genes.	No known proposals to create such transgenic human embryos or human beings.
Transgenic animal (with some human genetic material)	An animal embryo with human genes inserted.	An animal developed from an animal embryo that has integrated human genes.	Transgenic animals with human genetic material are widely used as disease-specific research models and many examples exist. One such example is the Oncomouse.

However, the scope of the HA Consultation Paper is much narrower in order to aid comprehension and facilitate discussion. In narrowing down the possibilities, all categories of human-animal combinations that either did not draw any scientific interest or were ethically less controversial were excluded. Transgenic animals have not been included in the HA Consultation Paper, as those routinely used in research tend to carry a very small number of human genes and hence not considered to be ethically controversial. However, transgenic animals could be a matter for future deliberation if whole human chromosomes are incorporated into non-human animals. As for transgenic humans, there is no known scientific interest in such experimentation. Being a matter of public policy, it would not be necessary to consider all the types of human-animal combination that can be created, even if there might have been academic reasons to do so. Even in the broader deliberation of other policy bodies such as the AMS, the contingency of free roaming human-animal creatures was precluded as the subject matter was mainly confined to embryos.

Apart from narrowing the scope through the categorical exclusion of certain human-animal combinations, a processual limitation has also been adopted in that only ‘human-to-animal’ combinations would fall within its purview. A chimera or hybrid could arise through the incorporation of animal materials into human (‘animal-to-human’ or ‘human’ chimera), or through the incorporation of human materials into animals (‘human-to-animal’, or ‘animal’ chimera or hybrid). Focus would only be on the latter process as the former was either ethically unambiguous at that time or already captured within an existing regulatory framework. For instance, the creation of an animal cytoplasmic hybrid (by introducing an animal nucleus into an enucleated human egg) would be unethical as the scarcity of human eggs implied that eggs

should not be 'wasted' unless there is overwhelming scientific imperative. As for any research on human embryos, specific approval from the MOH is required. Hence, any attempt to create a human embryo with non-human material could only be done with the approval of the Ministry. Similarly, the incorporation of animal materials into human at any point from the fetal stage of development would be regulated as research involving human subjects. With the successive narrowing of focus and the exclusion of theoretical possibilities from current consideration, the broad scope of 'human-animal combinations' was cropped down to 'human-to-animal' chimeras (or animal chimera) and cytoplasmic hybrids.

The much narrower scope is apparent in the table on the types of human-animal combination set out in the HA Consultation Paper (see Table 3).[149] Although 'transgenic animals' are included in the table, they have not been considered in the HA Consultation Paper, but serve only to emphasize that they have not been considered to "raise any new ethical difficulties."[150]

[149] Bioethics Advisory Committee, Singapore, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*, 8 January 2008, at 15.

[150] *Ibid*, at 13, paragraph 14.

Table 3. Creation and Use of Chimeras and Cytoplasmic Hybrids

	How it is created	Examples of use in research
Animal Chimeras	By introducing human cells, usually stem cells, into an animal or an early animal embryo or an animal foetus.	Testing the developmental potential of human stem cells or their derivatives. Evaluating the potential usefulness and safety of transplanting human stem cells for clinical treatment. *In vivo* drug testing giving an approximation to human responses. Studying the possibility of growing human tissues and organs in animals for the purpose of transplantation into humans.
Cytoplasmic hybrid embryos	By the transfer of the nucleus of a human somatic cell into an animal egg from which the nucleus has been removed (see Figure 2 [of HA Consultation Paper]).	A source of pluripotent stem cells for research. Studying the processes involved in nuclear reprogramming. A source of disease-specific stem cells for the study of specific disease processes and methods of treatment.
Transgenic animals	By introducing human genes into an animal embryo.	Routinely used in research to understand the cause of diseases, to develop more effective treatment for these diseases, to test the safety of new products and vaccines, and to study the possibility of producing organs for transplantation that will not be rejected.

Given the narrower focus, the HA Consultation Paper could have been re-titled ‘chimeras and hybrids’. However, a generic expression like ‘human-animal combinations’ was considered to be more neutral than an explicit reference to ‘chimeras’ and ‘hybrids’.[151] In addition, if the draft consultation paper was to be renamed ‘chimeras and hybrids’, it could be confused with the recently concluded public consultation of the HFEA. Hence in spite of the narrower focus of the draft consultation paper, the title of ‘human-animal combination’ was used. A further possibility was for the term ‘inter-species cell transplantation’ to be used in place of ‘chimera’, since the

[151] Fieldnotes, 21 August 2007.

latter was regarded as emotionally charged and carried negative connotations.[152] However, such a terminological substitution might be perceived as an attempt to sidestep ethical controversy by using a different label for something generally understood as referring to chimeras. Given that the term 'chimera' has already been used in a variety of literature to refer to the mixing of human and animal biological materials at a cellular level, the terminology was used.

2.3 Ethical Evaluation in the HA Consultation Paper

The ethical discussion in the draft consultation paper was similarly focused on narrowing the scope of the discussion to those that relate to the types of hybrids and chimeras of interest at that time. In particular, it was directed at refuting what Leon Kass – Chairman of President George W Bush's Council of Bioethics from 2002 to 2005 – regarded as the 'Wisdom of Repugnance'. Kass argues that we shudder at the prospect of human cloning not because of the novelty of the technology, but because "we intuit and feel, immediately and without argument, the violation of things that we rightfully hold dear."[153] If cloning causes one to shudder, the prospect of human-animal chimeras and hybrids will quite possibly create convulsions. Some scholars provide convincing reasons not to dismiss feelings lightly, even if they were merely initial reactions. For example, following Martin Heidegger and Maurice Merleau-Ponty, Kim MacLauren argues that emotions are not located in some 'solipsistic consciousness' but in our embodied engagement

[152] Fieldnotes, 14 November 2007.
[153] Leon R. Kass. The Wisdom of Repugnance, *New Republic* (2 June 1997) 216, 22: 17-26.

with the world and with others.[154] In addressing this reaction, a moralistic attitude was not adopted as this would come across as fundamentally dismissive of emotional expressions.[155] The problem with reactions of disgust, repugnance or like feelings is that they are a poor guide to collective action and public policy. Their seemingly subjective character further impedes an appropriate legal response given the impersonal nature of law. Such feelings could well be related to political and ideological views of the world, but both feelings and views change over time.[156] There also did not appear to be any effective policy means to address purely emotional concerns. On this rationale, the BAC considered emotional neutrality in ethical discussion to be a balanced manner in setting out and addressing commonly articulated or anticipated concerns and fears.[157] Substantive issues have been introduced and counter-arguments presented in order for the discussion to be rounded on the whole. Still, in a meeting with religious group leaders on 13 August 2008, it was observed by some that the ethical discussion in the HA Consultation Paper came across as 'consequentialist' in general orientation. This perception may be attributable to the categorical (and taxonomic) approach that sought to balance current and potential uses against anticipated risks. This was also a critique, by some bioethicists, of Henry Greely's allegedly utilitarian approach.[158] It is questionable if public policy could comprehensively

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154 Kim MacLaren. Emotional Metamorphoses: The Role of Others in Becoming a Subject, in *Embodiment and Agency*. In Sue Campbell, Letitia Meynell and Susan Sherwin (eds). University Park PA: The Pennsylvania State University, 2009, pp 25-45, at 26.

155 MacLauren indicates that emotional responses are often assumed to be simply irrational ways of configuring reality, and that a person already knows better, or already has access to the 'rational' response. *Ibid*, at 43.

156 Dan Jones, Moral psychology: the depths of disgust, *Nature* (14 June 2007) 447, 7146: 768-771. Jones writes (at 771): "…data from psychology and neuroscience should make us think twice about drawing on revulsion as a basis for our personal moral judgements. History seems to bear this out. Women (especially menstruating ones), the mentally and physically disabled, and inter-racial sex have all been viewed with disgust, and are still viewed as such by some…If disgust wasn't a good moral indicator then, why should it be now?"

157 Fieldnotes, 21 August 2007.

158 Françoise Baylis and Jason Scott Robert. Part-Human Chimeras: Worrying the Facts, Probing the Ethics, *American Journal of Bioethics* (2007) 7, 5: 41-45. Baylis and Robert state (at 44): "…the general utilitarian framework relied upon by Greely and colleagues in their analysis of the ethics of creating human neuron mice…is not, in our view, sufficiently rich as to capture the range of ethical concerns. The ethical concerns with this research are not just about weighing putative harms and benefits…chimeric research raises deep

capture all ethical concerns.[159] As the HA Consultation Paper sought to update the SC Report, the principles of justness and sustainability continue to guide the BAC's deliberation.[160]

The application of these principles is evident in the ethical identification of interests. An issue arose as to whether a discussion of 'Imago Dei' (Image of God) from an expert paper should be incorporated into the HA Consultation Paper. The concern was that this would be too targeted at a particular community (ie those of the Christian faith).[161] There is no similar concept of 'Imago Dei' in the Islamic faith, and although there are deities with human-animal forms in Buddhism and Taoism, this did not necessarily imply that Buddhists and Taoists would be more receptive to research involving human-animal combinations since the mixing of human and animal features tend to have negative connotations in Chinese culture. This concern did not find ready or expedient solution, but the discussion on 'Imago Dei' was not specifically raised in the HA Consultation Paper. It was nevertheless implicit in the ethical discussion on objecting to the research due to repugnance or 'playing God'.[162] The fact that 'God' has been set out in upper case suggests the Abrahamic conception of a monotheistic deity.

As the intent was to keep discussion in the HA Consultation Paper open-ended, effective regulation was more difficult to present as it could be seen as pre-empting the discussion if

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philosophical questions about what it means to be human and these questions cannot be addressed by appeal to utility maximizing strategies."

159 Interview with Associate Professor John Elliott, former member of the BAC and a member of the Secretariat, 27 August 2009.

160 The BAC indicates that its recommendations are intended to lead to results that are 'just' and 'sustainable'. The former favours research with tremendous potential therapeutic benefits to mankind while the latter requires research to have little biological or genetic impact on future generations. See Bioethics Advisory Committee, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*. Singapore: Bioethics Advisory Committee, 21 June 2002, at 35, paragraph 47.

161 Nuyen AT. Stem Cell Research and Interspecies Fusion: Some Philosophical Issues, 2007, at 3. Available at http://www.bioethics-singapore.org.

162 Bioethics Advisory Committee, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 8 January 2008, at 20-22.

specific regulatory approaches were proposed.[163] The significance attributed to regulatory control was nevertheless clear.[164] Instead of recommending specific regulatory approaches, regulatory principles were discussed.[165] The BAC indicates that research involving human-animal combinations should – as a baseline standard – remain governed within an existing ethical framework. Under the framework proposed by the ISSCR, four factors to be taken into account in the creation of human-non-human primate neural tissue chimeras via the implantation of human neural stem cells into an animal are stated essentially as scientifically-grounded ethical considerations. These factors, adopted by the BAC as ethical premises, are:[166]

1. Proportion or ratio of human to animal cells in the animal's brain;
2. Site of integration of the human neural cells;
3. Recipient species; and
4. Brain size of the animal involved.

Ethical constraints are also not clearly distinguished from regulatory measures in the HA Consultation Paper. Instead, ethics was in effect regarded as regulatory, for reasons to be considered in Chapter 4. Not surprisingly, the Executive Summary of the HA Consultation Paper emphasized that ethical constraints should be effective *as* regulatory safeguards in the event that research involving human-animal combinations is allowed. It was also made clear what would not be permitted, such as allowing human-animal combinations to develop to term or for them to be implanted into a womb. The possibility of setting out regulatory parameters to enable the

163 Fieldnotes, 14 November 2007.
164 *Ibid*.
165 Bioethics Advisory Committee, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 8 January 2008, at 27, paragraph 56.
166 *Ibid*, at 23, paragraph 43.

measured advancement of science was used against the 'slippery slope' concern, which will be elaborated on below.[167]

2.4 Reaction from the Scientific Community

As discussed in the previous Chapter, the SC Report specifies the categories of stem cell research that are permitted under varying degrees of regulatory purview. One such categories relates to the creation of human embryos specifically for research, which can only be justified under relatively stringent conditions, including the absence of an acceptable alternative.[168] The requirement of 'no acceptable alternative exists' is ambiguous as it would depend on who decides on what is acceptable. It could now be given a very restrictive reading by IRBs, in view of iPSC technology that has recently gained prominence. It is also ambiguous as to whether the three conditions set out for the creation of an embryo for research are applicable only to embryos created by SCNT or more generally to the creation of embryos through the combination of gametes. The creation of embryos for research by SCNT could be interpreted as being subject to a more stringent requirement than creation of embryos by other means, such as IVF.

It used to be thought that a main source of pluripotent stem cells would be embryos. And if such pluripotent stem cells were to be patient-specific, then SCNT was considered to an important technique that would enable the derivation. However, in November 2007, a group of Japanese

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167 *Ibid*. at 29, paragraphs 60-63.

168 Bioethics Advisory Committee, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*. Singapore: Bioethics Advisory Committee, 21 June 2002, at vii (Recommendation 5).

researchers announced a means by which human pluripotent stem cells could be derived without using embryos.[169] In essence, adult dermal fibroblasts (skin cells) were re-programmed (induced) to function like pluripotent stem cells through the use of viral factors. This represented an important proof of principle that pluripotent stem cells can be generated from somatic cells by the combination of a small number of factors. Such cells were referred to as iPSC.

This development immediately raised a question as to whether SCNT has been rendered obsolete. It was at that time still unclear if the technology could be used to derive human iPSCs from other types of human tissue. Even if this could be done, the level of pluripotence of iPSCs may not be as effective or efficient as stem cells derived through SCNT. Despite these uncertainties, the BAC did not delay its planned public consultation on human-animal combinations. It provided this explanation in the HA Consultation Paper that it was in the public interest to allow research to progress on all fronts.[170]

Separately, the BAC conferred with its scientific advisers, and on their advice, a survey of stem cell researchers in Singapore was conducted to obtain more information on possible impact of iPSC technology, as well as the relevance and level of interest in research involving human-animal combinations. A questionnaire comprising six questions was sent to 68 stem cell scientists. These scientists were identified from a researchers' database maintained by A*STAR and the Stem Cell Club's List of Group Leaders. They were contacted through email and the questionnaire was attached together with some reference materials. A total of 30 responses were

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169 Takahashi K, *et al.* Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors, *Cell*, 131, 5 (2007): 1-12. See also Yu J *et al.* Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells, *Science* 318, 5858 (21 Dec 2007): 1917-1920.

170 Bioethics Advisory Committee, Singapore, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 8 January 2008, at 11, paragraph 8.

received (or 44%), which the BAC considered to be a good response rate. Of these, only four of the thirty researchers who responded used human-animal combinations in their research. However, the respondents were mostly in support of the use of human-animal combinations in research. Two main points were highlighted in almost all the responses, regardless of whether they were for or against the use of human-animal combinations: the first was the need for clear and effective regulation, and the second was the importance attributed to informing and engaging the public on the subject.

Some respondents were not supportive of engaging in research involving cytoplamic hybrids and argued that greater investment should be channeled into iPSC technology. However, there is also an understanding in scientific ventures that it is important not to close an alternative until it is known with certainty that the favored method actually works.[171] If iPSC technology should prove to be the better method, then nuclear transfer technology would be redundant, given that it is ethically contentious and inefficient in deriving embryonic stem cells. In retrospect, this policy orientation has been vindicated as recent research suggests that iPSC cells have characteristics that are different from SCNT cells. Feedback from stem cell researchers also suggested that the requirement of "no acceptable alternative exists" was considered to be ambiguous as it would depend on who decides on what is acceptable. In addition, it might be given a very restrictive reading by IRBs, particularly in view of iPSC technology. It is also questionable as to whether the hierarchy of sources for human embryonic stem cells[172] remains relevant (ie a concept that surplus embryo should be used before an embryo may be created for research). One view is that

[171] Fieldnotes, 16 January 2008, M2.

[172] Bioethics Advisory Committee, Singapore, *Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*, 21 June 2002, at vii, reading Recommendations 4 and 5 of the Stem Cell Report together.

there are insufficient left-over embryos from IVF treatment for research. Most of these embryos are not donated for research, and this problem is not peculiar to Singapore. Thus the statement that: "As long as there are sufficient and appropriately donated surplus embryos from fertility treatments available for use in research…"[173] could be inaccurate in the light of current experience. An advisor to the BAC observed that it is not only a question of numbers.[174] Potential uses of stem cells include allowing researchers to study and understand the processes in developmental biology, to test new drugs, and to generate cells and tissues for therapy.

Apart from the issues already highlighted in the survey, feedback from researchers during the public consultation raised a concern over 'red-tape'. This concern over the burdening of research involving human-animal combinations that are already commonplace in the scientific world prompted the BAC to meet with senior stem cell researchers in May 2009. In that meeting, researchers were of the view that standard types of human-animal combinations should not require extensive ethics review. As such, it would be necessary to demarcate clearly between chimeras that are routinely created, such as those created as a result of a standard scientific procedure like teratoma testing, from less conventional research like SCNT. For 'non-conventional' human-animal combinations such as cytoplasmic hybrids, the researchers agreed that more detailed ethical scrutiny may be required. For instance, a researcher may want to take progenitor cells from a patient with leukemia and put these into a mouse. While it is highly unlikely that human DNA will enter into the germline of the mouse, this possibility could not be completely ruled out. Like stem cells, progenitor cells have the capacity to differentiate into specific cell types. Hence such research was considered to be a borderline case and might require

173 *Ibid*, paragraph 30, at 28.
174 Interview with Professor Martin Bobrow, 19 January 2008.

full ethics review, although it should be noted that such a mouse will not be allowed to breed, and will be confined to a laboratory environment. The use of pluripotent cells in neurological research should also require ethical review. It was noted that the first human trial has been started by Geron and the implications of such neurological research will have to be carefully considered.[175] The researchers further recommended that the BAC highlight issues for an IACUC to decide, as it knows of the exact extent of research that could be done on laboratory animals. A researcher noted that "the IACUC counts all mice".[176] Hence more interaction between the IACUC and IRB could avoid duplicative review. However, another researcher said that, from his experience as a member of an IACUC, all research involving human cells will have to be reviewed by an IRB.[177] As such, it will be difficult to exclude either the IACUC or the IRB from reviewing a research proposal involving human-animal combinations.

Notwithstanding iPSC technology, there is a continuing need for ethical guidance on embryo research. Despite strong research interest in iPSC technology, ethical concerns with embryonic stem cell research would not be extinguished as 'engineered' oocyte and sperm created through iPSC could be used to create an embryo, thereby giving rise to a whole range of related issues. However, the level of research interest in creating an embryo through such means was unclear. A researcher was of the view that there would be research interest in the near future (in about 2 to 5 years' time) in creating embryos through iPSC technology given the increasing popularity of stem cell therapy.[178] It was further observed that induced pluripotent stem cells could be

[175] Geron, Geron Initiates Clinical Trial of Human Embryonic Stem Cell-Based Therapy, Press Release, 11 October 2010.
[176] Fieldnotes, 26 May 2009, HH.
[177] Fieldnotes, 26 May 2009, PR.
[178] Fieldnotes, 26 May 2009 (MK).

imported into Singapore for the purpose of deriving stem cell lines from embryos thereby created as this did not fall within any regulatory control.

The BAC's plurality of approaches was also supported as researchers generally recognized that SCNT remains a useful technology. Reprogramming research should be allowed so long as the technology is not applied for reproduction, but the shortage of human oocytes will continue to be a major problem. In relation to the regulatory environment, the researchers did not consider the current regulations to be prohibitive of research involving human-animal combinations, although they were concerned that some aspects of the research may become over-regulated. The proposal to establish a central or national ethics review body for stem cell research was supported by the researchers. Currently, the efficacy of ethics review was felt to vary with different reviewing officers since their familiarity with the subject matter and the standards entailed differ. In addition, different IRBs have different 'house rules' and many IRBs are constituted by medically trained professionals who might not fully appreciate the research requirements of scientists.

My sense of the meeting is that the researchers took a very practical and personal view of the issues as they did not want to speak on behalf of their community (which could be broadly associated with the Stem Cell Society). Hence they did not venture any opinion on what their peers were or were not interested to do. Although the BAC's decision to ask the researchers where the boundaries should be drawn is a sensible one, these were not the types of questions that researchers wanted to answer. The term 'human-animal combination' was somewhat confusing to them because they did not regard a chimeric mouse created as a means of testing pluripotency to fall within the definition - as conceived by them. Such a biological construct was

to them a ‘standard practice’ in the field and should not be burdened with strict ethical scrutiny. From experience with such research, they appeared uniformly concerned about over-regulation. To some degree, this concern was justified. All stem cell research would have to undergo IRB review under the existing IRB guidelines issued by the BAC. As the existing guidelines do not provide for different standards of review for the use of established stem cell lines, a higher standard of review could be anticipated. With the benefit of experience, ethical review of certain types of embryonic stem cell research may be relaxed. There was some confusion over terminology when a researcher said he objected to research involving ‘human-animal combinations’. In the context of the discussion, he was likely to be referring to cytoplasmic hybrid, rather than a chimeric mouse for testing pluripotency - which he himself had a hand in creating. Once the matter of chimeric mouse as ‘standard practice’ was carved out of the rubric of ‘human-animal combinations’, the researchers did not disagreed with the overall regulatory orientation that the BAC had in mind, be it in terms of a proposed centralized regulatory mechanism, or in targeting specific areas for regulatory attention, such as research with neurological (hence sentience) and reproductive or germline implications. Their comments on the continuing relevance of ethical guidance and review for embryo research, notwithstanding the advent of iPSC technology, have been especially helpful in affirming the proposed approach of the BAC.

2.5 Between Humans and Animals

Cytoplasmic hybrid embryos constitute a relatively small and perhaps even niche area of research involving human-animal combinations. As discussed above, transgenic animals and chimeric animals or chimeras created through the introduction of human cells such as stem cells, into animals at various stages of development or the grafting of human neural cells into primate brains, constitute the largest group of human-animal combinations. In Singapore, the only regulation relating to such research was primarily concerned with animal welfare. Given this focus, a query arose as to whether there was a need for some sort of interface between the regulation of human subject research and the regulation of animal research. Following the closure of the public consultation on the HA Consultation Paper, the HECR Working Group met with the NACLAR. NACLAR was established in 2003 to develop national guidelines for the care and use of animals for scientific research. On October 2004, it issued a set of guidelines that addresses all aspects of the care and use of animals for scientific purposes.[179] The principles of replacement, reduction and refinement have been stated as encapsulating the guidelines. In 'replacement', researchers are encouraged to consider alternatives to animal models, and thereby 'reduce' the number of animals used. Where animals are used, projects and techniques should be 'refined' to minimize impact on animals. The NACLAR guidelines require all research facilities that house and use animals for scientific purposes to establish an IACUC, which is responsible for the oversight and evaluation of animal care and use programs of the institution. In order to qualify for licensing from the AVA, it is a requirement for these research facilities to comply with the guidelines.

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[179] National Advisory Committee on Laboratory Animal Research, *Guidelines on the Care and Use of Animal for Scientific Purposes in Singapore*. Singapore: National Advisory Committee on Laboratory Animal Research, 2004.

The meeting of the HECR Working Group with the members of NACLAR proceeded in a fairly structured manner, following a series of questions presented by the BAC for discussion prior to the meeting, alongside public feedback (to be discussed below) relating to animal welfare and care. The first question related to the nature of a cytoplasmic hybrid embryo, and whether it should be regarded as predominantly human for regulatory purposes. Under the (then proposed) UK amending legislation on the subject,[180] a human 'admixed embryo' will fall within the regulatory purview of the HFEA regardless of the extent of admixture if the proposed legislation is to be a classificatory guide.

The Chair of NACLAR explained that it was formed for the purpose of establishing guidelines for the use of laboratory animals in research.[181] The AVA, which NACLAR advises, is the implementer of the guidelines. Human-animal combinations were considered to fall outside the guidelines unless they have an impact on animal welfare. If a cytoplasmic hybrid 'embryo' is considered 'human' for regulatory purposes, then it would fall outside of the NACLAR guidelines. In addition, the NACLAR guidelines apply only to subjects that are legally defined as 'animals' and do not apply to 'embryos'. NACLAR members further indicated that the guidelines would not ordinarily apply when animal material is used unless an animal is involved. If human material is introduced into an animal, the NACLAR guidelines would apply as animal welfare is in issue. If human material is introduced into an animal embryo or fetus, and then allowed to develop into a live animal, the NACLAR guidelines would also apply. It follows that the welfare of an animal, as donor of embryos, is similarly covered by the NACLAR guidelines.

180 UK *Human Fertilisation and Embryology Bill*, HL Bill 6, 2007-8.
181 Fieldnotes (BT), 15 April 2008.

However, as a cytoplasmic hybrid embryo will not be implanted, animal welfare is unlikely to be a concern.

The next two questions related to the extent of regulation considered to be appropriate. In the absence of sound scientific rationale for mixing human and non-human gametes, it was queried if the creation of true hybrids through means such as this should be prohibited by law. If such a research avenue should not to be proscribed, it was then queried if there should be any requirements for ethics review that will be different from the existing requirements for ethics review, in respect of experiments using or creating humanized animals (chimeras or transgenic animals). The concern among some researchers in Singapore that this arrangement might lead to greater bureaucratization of the ethics review process was also highlighted.

The meeting found the DCE's deliberation on this issue (discussed in Chapter 3) to be persuasive, and NACLAR agreed that the creation of true hybrids by mixing human and non-human gametes for reproductive purposes should be prohibited by law. In addition, NACLAR also agreed that while the creation of an animal that is partly humanized with a view to obtaining new knowledge about therapeutic possibilities should not be prohibited, both a scientific-ethical committee (or an IRB) and the Animal Experiments Inspectorate (or IACUC) must give permission for the experiment.[182] On the concern with greater bureaucratization, humanized animals such as SCID-Hu mice are commonly created, and the NACLAR guidelines sought to secure the welfare of the animal through measures such as requiring tests to ensure that the animal did not become infected with human pathogens. Insofar as the creation and use of

[182] Danish Council of Ethics (with the Danish Ethical Council for Animals). *Man or Mouse: Ethical aspects of chimera research*. Copenhagen: Danish Council of Ethics, 2007, at 39.

humanized animals were already addressed by the NACLAR guidelines, a new set of guidelines was unlikely to be required. As such, concern over greater bureaucratization of the ethics review process was not considered to be well grounded. NACLAR members further indicated that it has adopted the de-centralized approach of Australia, Canada, New Zealand and the US, preferring self-regulation by institutions handling laboratory animals to the UK practice of licensing at different levels.

On the prospect that research involving human embryonic stem cells and the introduction of such cells into animals (or *vice versa*) may be reviewed by a centralized ethics body rather than different institutional review boards, NACLAR members were of the view that the existing framework for animal ethics review through the IACUC should be retained. This is consistent with the recommendation of the ISSCR for ethics review of research involving human embryonic stem cells to be centralized (discussed in Chapter 3), but animal ethics will continue to be reviewed within the institutions concerned. A NACLAR member emphasized that bureaucratization of any process in animal ethics review should be avoided as far as possible and the preference is for the IACUC to remain instead of a centralized ethics body.[183]

On the scope of the prospective report, the view of NACLAR was sought as to whether a distinction should be drawn among different types of animal recipients such as mouse as opposed to primates. A related issue was whether the introduction of a substantial amount of human material into an animal should be of regulatory concern. Similar to a number of other respondents, NACLAR perceived a need to distinguish among different types of animal recipients, such as primates, largely on the basis of evolutionary biology. In addition, the

[183] Fieldnotes (BO), 15 April 2008.

introduction of a substantial amount of human material (such as human neurons) into an animal could be of regulatory concern. The extent to which a chimeric embryo is allowed to grow is still unclear, and such an embryo is usually terminated before birth. It was observed that the number of experiments involving the introduction of human embryonic stem cells into animals to test for pluripotency and to determine experimental conditions required for cell differentiation is likely to increase. For this reason, scientists will require clear guidelines on permissible research, such as the extent to which human neurons may be introduced into an animal.

There was ambiguity over what should be done if an animal with human sentience should emerge. Some members of NACLAR felt the threshold for the care of this animal may have to be increased. Even then, the baseline of care for the animal would still apply. If it is to be euthanized, this should be carried out in accordance with internationally accepted standards. As to how 'sentient' a chimeric animal is allowed to be, this would be an issue for the IRB, rather than an IACUC, to decide. A HECR Working Group member indicated that there should not be a need to develop a formalized set of procedures directed at a chimeric animal with human sentience as this outcome should be avoided at the point of initial review. However, in the event that a sentience creature emerges without any known cause, then there should be a mechanism to address this particular contingency. In other words, this 'adverse outcome' should be handled on a case-by-case basis, rather than by general regulation. It may be considered unethical for such an animal to be euthanized like any other laboratory animal. A NACLAR member maintained that even in such a case, it is still an animal and that there are countries that allow human beings to be euthanized.[184] Another NACLAR member indicated that the situation is less clear in law, as an animal with human sentience would fall within a legal lacuna. It would arguably not be an

[184] *Ibid*.

'animal' contemplated under the Animals and Birds Act,[185] and would thereby be outside of the regulatory purview of the AVA. It would be for the BAC ("or some higher level") to decide whether such a contingency should be anticipated in regulation, or it should be managed if and when it materializes.[186] It was felt that the latter option is preferable since Singapore has a more tightly regulated environment than a country like the US, where regulations would cover only certain animals unless the research is federally funded. With better control in Singapore, it was observed that regulatory oversight should not be overly prescriptive. For instance, it would be difficult to distinguish 'humans' from 'animals' by way of guidelines without being unduly prescriptive. Self-regulation was regarded as the best way to avoid stifling research.

The necessity of including transgenic animals in the prospective HA Report was also raised. It was noted that transgenic animals have not been considered in the HA Consultation Paper although they have been identified by the AMS and the DCE for future consideration.[187] NACLAR indicated that a transgenic primate might raise more ethical concerns than a chimeric primate. For this reason, the oversight mechanism for transgenic animals would likely be different from a mechanism for chimeric animals, and a separate regime should be developed.

The remaining segment of the discussion was concerned with feedback received from the public consultation. The Life Sciences Institute (NUS) indicated in its feedback that pre-mature termination (or euthanasia) should be encouraged. While the creation of human-animal

185 Singapore Statutes: *Animal and Birds Act* (Cap. 7), 2002 Revised Edition.
186 Fieldnotes (EC), 15 April 2008.
187 The Academy of Medical Sciences, UK, *Inter-species embryos: A report by the Academy of Medical Sciences.* London: Academy of Medical Sciences, June 2007, at 40, and Danish Council of Ethics and the Danish Ethical Council for Animals, *Man or Mouse? Ethical aspects of chimera research*. Copenhagen: Danish Council of Ethics, 2007, at 10.

combinations is not opposed, researchers are strongly encouraged to seek alternatives to painful procedures, and to develop endpoints and criteria for premature termination as in Europe and America. Death as an endpoint is strongly discouraged.[188] NACLAR members indicated that such a standard has been provided for in the existing NACLAR guidelines, which states: "Death as an end-point must be avoided if at all possible. If death as end-point must be used, the Investigator must ensure that the animal's distress or pain is minimized and use appropriate sedation, analgesia, or anesthesia to relieve the animal's distress or pain."[189]

It was further noted in the discussion that feedback received on this issue has highlighted the need to ensure that chimeric animals (i) do not breed, (ii) be confined within a laboratory environment (and so do not enter the food chain), and (iii) suitably comprehensive tests for pathogens should be carried out on cell lines and tissue used in human-animal combinations, as established cell line producers such as ATCC[190] may not run sufficiently complete tests for pathogens. In essence, there was an indication that additional laboratory requirements might have to be introduced. However, NACLAR members were of the view that the existing guidelines should adequately address animal ethics concerns, including the contingency of a research animal (chimeric or not) escaping from a laboratory environment. The security of the research facility is one component of the site inspection carried out by the AVA. In addition, laboratories have protocols to deal with such a contingency. A NACLAR member again emphasized that the regulatory environment in Singapore should not be unduly restrictive. Human-animal chimeras

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188 Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at C-13-1 to C-13-4.

189 National Advisory Committee on Laboratory Animal Research, *Guidelines on the Care and Use of Animal for Scientific Purposes in Singapore*. Singapore: National Advisory Committee on Laboratory Animal Research, 2004, para 2.2.4 (h).

190 ATCC (or American Type Cell Culture) cell lines are commercial cell lines generally recognized to have satisfied ethical requirements in their derivation.

that are already commonly created and used should not be burdened by additional regulatory control. From separate interviews with researchers, NACLAR's concern about over-regulation appeared to be supported by a number of leading stem cell researchers, one of whom suggested that the IACUC he worked with "…treated mice like they are humans",[191] and another said that his (institution's) IACUC "counted all mice".[192]

Human-animal combinations bring to mind Jacque Derrida's critique of the institution of speciesism in his neologism of *l'animot*. He argues that "[a]mong non-humans and separate from nonhumans there is an immense multiplicity of other living things that cannot in any way be homogenize, except by means of violence and willful ignorance, within the category of what is called the animal or animality in general…The confusion of all nonhuman living creatures within the general and common category of the animal is not simply a sin against rigorous thinking, vigilance, lucidity, or empirical authority; it is also a crime."[193] Certain 'constructs' of interspecies combination such as a human being with pig's heart valve have been controversial, but they did not otherwise pose a serious threat to the moral and social boundaries that distinguish 'humans' from 'animals'. However, human embryonic stem cell technology has enabled a level of cellular integration between human and non-human animals that was not previously thought possible. For instance, human embryonic stem cells may be introduced into an animal embryo in order to study the development of particular diseases or in the creation of disease models. Once introduced, the dispersion of human cells within the animal embryo will be difficult, if not impossible, to control. More critical is that the level of integration between

[191] Interview with Professor Davor Solter, 22 February 2010.
[192] Fieldnotes, 26 May 2009 (Dr Hannes Hentze).
[193] Jacque Derrida (trans. David Wills). The Animal That Therefore I Am (More to Follow), *Critical Inquiry* (2002) 28: 369-418, at 416.

human and non-human embryonic cells is expected to be profound, giving rise to a real concern that a creature with human features could be created if the embryo is drawn from an animal that is close to humans in evolutionary terms (such as primates). In other words, interspecies combinations generate a deconstructive force so strong that 'humans' again come face to face with its 'Other' in 'animals'. This is the great paradox that we witnessed in Darwinian deconstructionism in *On the Origin of Species* that contributed to a fundamental shift within the law from naturalism to positivism. As legal historian Michael Stolleis points out, the natural law (and naturalism in law) has itself arisen from a shift away from the 'Law of God' in the religious crisis of sixteenth and seventeenth-century Europe.[194] With the ascent of natural science, and "the notion of the 'state as machine' functioning according to the rules of the natural sciences[,] …jurists so optimistically sought their metaphors and analogies" in that field.[195]

As we have seen, STS scholars provide convincing arguments that in getting behind scientific objectification, we find a naturalcultural mix that in turn points to far more fluid ways in which relationships among sentient beings and non-sentient objects could be organized. Legal objectification through laws that both secure animal welfare and enable the utilization of animals to meet certain human needs share some commonalities with scientific objectification. The challenge posed by human-animal combinations to the often assumed clarity of the distinction between humans and non-human animals represents the naturalcultural mix that objectification conceals. When the categorical breach first surfaced in science, the question of 'humanness' was transposed to ethics. Science has in that sense insulated itself from the paradox by labeling this

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194 Michael Stolleis, The Legitimation of Law through God, Tradition, Will, Nature and Constitution. In Larraine Daston and Michael Stolleis (eds), *Natural Law and Laws of Nature in Early Modern Europe: Jurisprudence, Theology, Moral and Natural Philosophy*. Cornwall: Ashgate Publishing, 2008.

195 *Ibid*, at 52-53.

an ‘ethical’ rather than ‘scientific’ issue. It is not because scientists are ‘disinterested’, but science is itself incapable of providing a response from within its own knowledge field. Within ethics (as we shall see), a rationalizing process through categorization and systematization has been initiated to shield ‘humanity’ from its ‘Other’ by reinvigorating a compromised ‘naturalism’. Arguably, there has been some level of success in demarcating the ‘sacred’ from the ‘profane’. In the process, ethics – like religion – has to transcend both the ‘Self’ and its ‘Other’ in the form of a Third. There are two problems here. First, the transcendence to a standpoint of the Third is also to transcend reason. Hence in so doing, ethics itself encounters its paradox. But while it may share some likeness of being with religion, ethics is not religion. This presents the second difficulty in that ethics is confronted by its own impotence. At the most practical level, ethics has limited recourse to the exercise of legitimate power. Ethics needs science in overcoming the first difficulty. The ethical category of ‘humanness’ is projected back onto scientific material so that the ‘rationality’ is regained. Ethics also needs law, and the unifying basis for both has been in the ‘common good’. Some perceive this union as consequentialist or utilitarian, based largely on a balance of perceived cost and benefit. But it is from this practical association that ethics switches back-and-forth with law, thereby allowing both to escape from the shocking encounter with its paradox. In a different context, Annelise Riles has evaluated a similar shifting in and out of the law as movements between normative and reflexive knowledge.[196]

Whether the BAC or NACLAR, policy bodies in Singapore and elsewhere appeared to have perpetuated the common perception of essentially two populations: of ‘humans’ and its ‘Other’.

[196] Annelise Riles, Representing In-Between: Law, Anthropology and the Rhetoric of Interdisciplinarity. *University of Illinois Law Review* (1994): 597-653, at 643-4.

This is similar the case in substituting older metaphors *of* chimeras and hybrids with new metaphoric models *for* these biological constructs. The 'crime' that Derrida speaks of is perhaps mitigated by the fact that less violence is inflicted in the erasure of the difference among species, and individuals of a species, within institutions that relate to 'humans' and 'animals' in biomedicine. Still, it is necessary to sustain a distinction between humans and non-human animals in order for current practices in science, ethics and law to make sense. In the law, sustaining the distinction between *persona* and *res* is a critical premise by which a certain moral and social order is maintained. But as we have seen, the Great Apes continue to haunt us; persisting within the great chasm that distinguishes 'humans' from its 'Other'. In the next Chapter, we will see that whereas some countries are prepared to allow some differentiation within the large category of 'animals' by distinguishing primates in particular, other countries like Singapore are not prepared to do so.

2.6 Categorization and Classification

Drawing up categories has been a useful approach to understanding chimeras and hybrids, and for me, in presenting them as legal 'objects'. Reflecting on the brief conversation that I had along a corridor at the Bukit Timah campus a little while back, legal categorization arises principally through legislation and adjudication. Clear rules set out the investitive conditions, which in turn create categories that define legal subjects and objects. Eric Mitnick explains:[197]

[197] Eric J. Mitnick. *Rights, Groups and Self-Invention: Group-differentiated Rights in Liberal Theory*. Cornwall: Ashgate Publishing, 2006, at 58.

> For the common law system of reference to precedents is based upon the principle of formal justice that like cases must be treated alike. Courts will thus determine any new claim of legislative right both with reference to explicit legislative criteria and by reasoning analogically from prior cases. The result, once again, will be a class of persons related by law one to another by virtue of some common characteristic(s). Indeed, even in the absence of legislation, adjudicative generality works to similar effect, though the investitive conditions tend necessarily to develop in the opposite direction…a right fashioned exclusively in adjudication begins with a particular claimant pressing a particular claim and then only gradually broadens into a rule of law.

As we have seen, the manner in which the BAC went about the analysis was to set out in taxonomies the types of chimeras and hybrids that occur naturally, those that have been created by scientists, and those that could be created. For instance, a pregnant woman is by definition a human-human 'chimera'. Being 'natural', this benign 'chimera' does not provoke any feeling of disgust in contemporary society. Hence 'natural' as opposed to 'unnatural' was a premise on which categorization was based, which also related to current and potential uses. Henry Greely's approach is similar in that he attempts to assess how taxonomy of chimeras might illuminate ethical issues that categories create.[198] He relied on four dimensions based on biological constituents, relationship between the organisms, how mixing is done and when it took place, and arrived at the conclusion that the ethical issues depend on the 'humanity', 'naturalness' and proposed uses of the chimeric organism.

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[198] Henry T. Greely, Defining Chimeras…and Chimeric Concerns. *American Journal of Bioethics* (2003) 3, 3: 17-20.

For the purposes of public consultation, a neutral definition of 'chimeras' and 'hybrids' in the Chinese language was thought to be necessary since the subject matter was already being discussed in that language forum. The expression '**嵌合体**' is commonly used in scientific and ethical discussions in both China and Taiwan, and is also the expression used in the newspaper commentary. In addition, this expression has been applied in a number of English-Chinese dictionaries. In Japanese, Kanji (old script Chinese) characters have not been used to depict 'chimera' although they are used for the more generic reference to 'cell' (细胞). Instead, the term 'chimera' is set out in katakana as '**キメラ**', which suggests the importation of a foreign terminology (and its corresponding meaning) into the Japanese lexacon. For instance, this term has been used by Japan's Ministry of Education, Culture, Sports, Science and Technology (文部科学省).[199]

Chimeras and hybrids are metaphors that enable the transmission of these concepts from myths and imagination to present day reality. Even though a chimeric mouse, let alone a cytoplasmic hybrid embryo, does not look anything like Homer's Medusa or the characters in the Chinese classic *Journey to the West* (西游记), the ontologically creative function of metaphors enable a cognitive equivalence to be drawn between the two metaphoric objects.[200] Hence in the public

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[199] See for instance, 文部科学省. 生命倫理及び安全対策に係る留意事項 [Ministry of Education, Culture, Sports, Science and Technology, Japan. Notice on Bioethics and Safety Considerations]. See also 文部科学省. 人クローン胚の研究目的の作成・利用のあり方に関する検討経緯等について [Ministry of Education, Culture, Sports, Science and Technology, Japan. Background discussion on the purposes and uses of human cloned embryos]. The reference to chimeric embryo in Japanese (キメラ) appears to be a more generic reference to human-animal combinations (嵌合胚胎) in Chinese.

[200] Relying on the seminal work of Max Black, Terrell Carver and Jernej Pikalo indicate that metaphors are creative-productive function that shape thinking on discourses and contexts. They also act as discursive nodal points. See Terrell Carver and Jernej Pikalo. Editors' introduction. In *Political Language and Metaphor: Interpreting and changing the world*, Terrell Carver and Jernej Pikalo (eds). London and New York: Routledge, 2008, pp 1-12, at 3-4. See also: Max Black. *Models and Metaphors: Studies in Language and Philosophy*. Ithaca and London: Cornell University Press, 1962.

imagination, the creation of chimeras or hybrids by scientists is no different from the creation of monsters (for instance, see Picture 1 below on images of chimeric creatures presented in a press report on the BAC's HA Consultation Paper). In fact, graphical illustrations were made by a member of the Secretariat during a discussion on how best to introduce a 'chimera' and 'cytoplasmic hybrid' (by considering how they could be created) to the public:

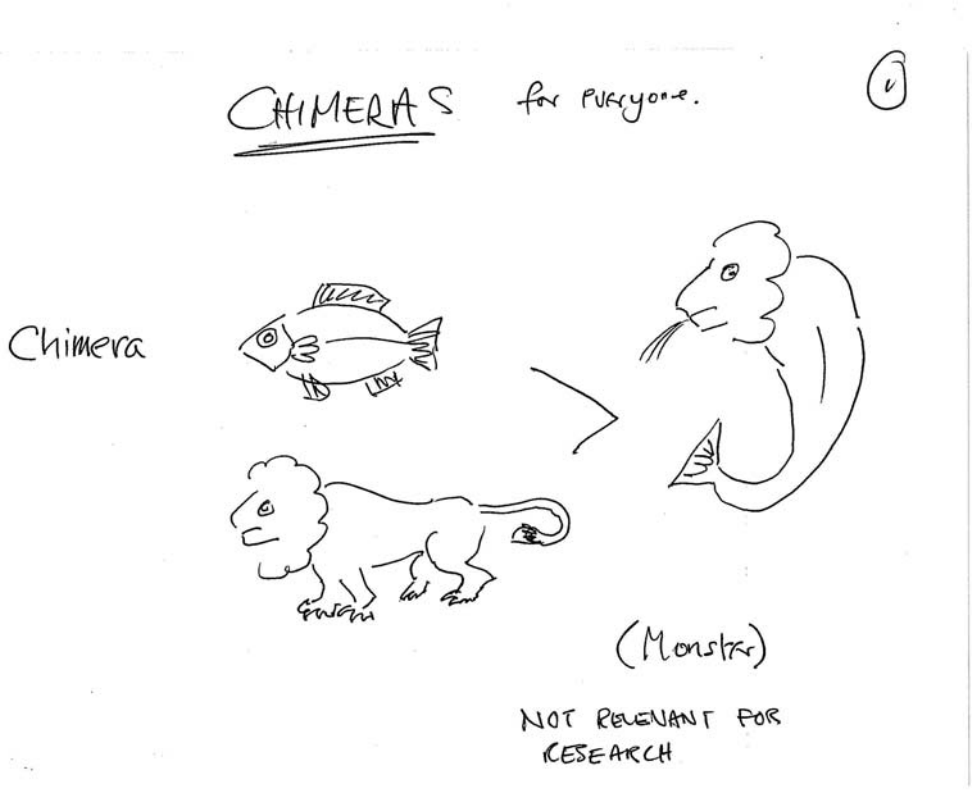

Illustration 1. Sketch of a Chimera

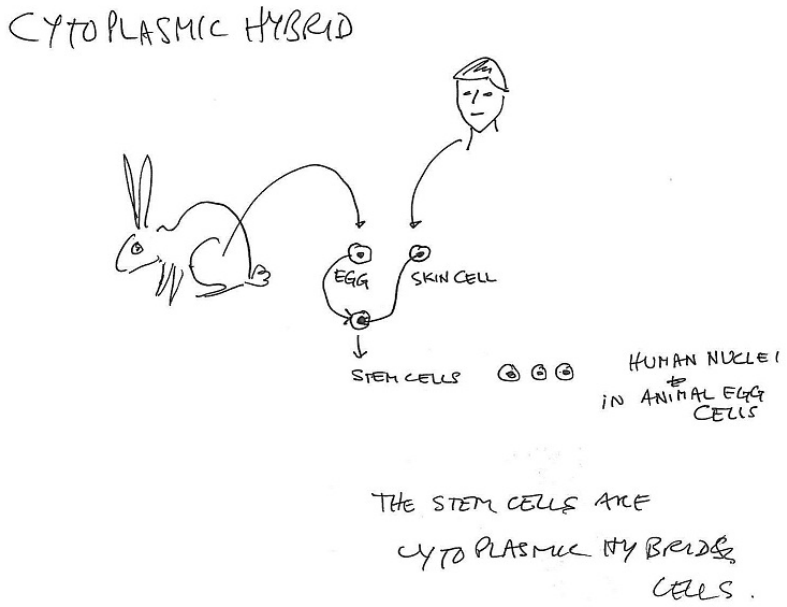

Illustration 2. Sketch of a Hybrid

Concerns over the pervasive metaphorical contents of chimeras and hybrids, a research group sponsored by the European Union considered the invention of a new term for these biological constructs necessary to address terminological problems.[201] The word 'Chimbrid' is used to denote any organisms created through the mixing of living human and animal biological material and dealt with in their report.[202] It is hence a term distinct from the common understanding of chimeras and hybrids that the project team regards as grounded in culture and mythology, and thereby inconsistent with science.[203] The recommendations put forward by this research group will be discussed in the next chapter.

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201 Jochen Taupitz and Marion Weschka (eds), *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009, at 5.

202 The Chimbrids team did observe that the scientific community was not unified on the distinctions between human and non-human chimeras: *Ibid*, at 16.

203 *Ibid*, at 13.

Veronique Mottier's observation that metaphors inform and structure thinking as 'mini-narratives' acting against a backdrop of tacit knowledge is pertinent.[204] These 'mini-narratives' have the capacity to form identities through discursive mechanisms of boundary-drawing, boundary maintenance, ordering and othering. A number of well-known Chinese didactical folklores with imaginary entities (that include foxes and ghosts) have these multifold, and evidently moralizing, functions.[205] In our present situation, the familiar mythical metaphors constitute the identities of the biological constructs. They posed the most direct and immediate challenge as models of some prior and typically unarticulated understanding of the phenomena – perhaps related in some way to the 'yuk' feeling that some have raised in opposition to the creation of human-animal combinations in research. Dvora Yanow defines 'models *of* prior conceptualization' as metaphors, or forms of 'seeing-as'. These metaphors "embody and reflect context-specific prior understanding of their subject matter, drawing – usually implicitly, through tacit knowledge – on metaphoric meaning in its source origins."[206] More insightful is her recognition that metaphors are also 'models *for*', in that "they embody seeds for subsequent, future action that follows from the underlying logic of the prior understanding on which they draw".[207] In order to counter the existing metaphors or models *of* chimeras and hybrids, it would be necessary to discredit them. Once discredited, these ideas would then have to be disembedded from the familiar mythical context and re-constituted within a new context that will enable the new to be understood in terms of the old. It may be inferred from the tabular display (Table 2) of

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204 Veronique Mottier. Metaphors, mini-narratives and Foucaldian discourse theory. In Terrell Carver and Jernej Pikalo (eds), *Political Language and Metaphor: Interpreting and changing the world*. London and New York: Routledge, 2008, pp 182-194, at 191-192.

205 Leo Tak-hung Chan. *The Discourse on Foxes and Ghosts: Ji Yun and Eighteenth-Century Literati Storytelling*. Hong Kong: Chinese University Press, 1998. See for instance, at 246-247.

206 Dvora Yanow. Cognition meets action: Metaphors as models of and models for. In Terrell Carver and Jernej Pikalo (eds), *Political Language and Metaphor: Interpreting and changing the world*. London and New York: Routledge, 2008, pp 225-238, at 227 (emphasis in original).

207 *Ibid*.

human-animal combinations that the new context is grounded in the rationalities of ethics and science combined, and applied toward the maximization of the common good (in that, the end goal is some therapeutic benefit). In contrast, the old context is projected as speculative, irrational and superstitious.

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MMS: 92288736

把人类细胞与动物结合，会制造出什么样的“人兽嵌合体”？（档案照片）

人兽嵌合体？

生物道德咨委会征询公众意见

许翔宇 报道
hsiangyu@sph.com.sg

干细胞研究近年来突飞猛进，但供科研用途的人类卵子不足，科学家于是把人类细胞植入动物卵子，以发展干细胞研究，你同意吗？

把人类细胞与动物结合，制造出“人兽嵌合体”，即所谓的chimera,这类研究是否应被禁止？如果被允许，我们要如何管制这类研究？

为了征询公众对这些课题的看法，新加坡生物道德咨询委员会（Bioethic Advisory Committee）发表了一份题为“供应生物医药研究的人兽嵌合体”的征询意见书。（Human-Animal Combinations for Biomedical Research – A Consultation Paper）。

生物道德咨询委员会在征询意见书中表示，“人兽嵌合体”可用来研发许多新疗法，治疗目前无法医治的疾病，如帕金森病症和老人痴呆症。

此外，将人类的基因植入动物体内，也可发展人类疾病的研究。

然而，人类扮演“上帝”，操纵大自然，会不会制造出有人类智慧的动物或怪物？混淆了人与动物的分界，会引发什么道德问题？如果要立法管制，要如何监管这类研究？

这些随之而来的道德、社会和立法问题都必须严肃看待。因此，生物道德咨询委员会欢迎公众针对上述课题发表意见。

生物道德咨询委员会主席林彬教授在下午开记者会，欢迎各界针对“人兽嵌合体”课题发表意见。

研究项目	研究原因
·将人类细胞植入兔子或牛的卵子 ·将人类干细胞植入老鼠脑部 ·制造含人类免疫系统的老鼠 ·以人类干细胞培育心脏细胞移植入老鼠心脏 ·羊身上有15%属人类器官	·从中培育干细胞，研究遗传性疾病如帕金森病症和老人痴呆症。 ·研究人类脑神经疾病的演变和疗法 ·研究爱之病和抗爱之病病毒药物 ·测定以干细胞治疗疾病是否安全。 ·研究在动物人体内培植人类器官，以供器官移植。

Illustration 3. Images of ‘Chimeras’ on newspaper coverage of BAC’s HA Consultation Paper

During the public consultation, the attempt to displace more commonplace notions of chimeras and hybrids was on the whole successful. It subsequently emerged during the public consultation that neither the English language nor Chinese language newspapers deployed the more common terminology 'chimera', but instead preferred a terminology that captured the essence of the biological construct. The English language papers used the term 'human-animal combinations' that was proposed by the BAC and attempted to present the discussion in relatively objective light. This was similarly the case for the mainstream Chinese language newspaper (联合早报) in Singapore.[208] Another two Chinese language newspaper attempted to sensationalize the subject with controversial cartoon pictures of creatures such as a pig with a human head, but the content of these articles was a reasonable presentation of the issues.[209] News reports from China, Taiwan and Hong Kong, as well as the news coverage by the main Chinese language newspaper in Singapore referred to human-animal combinations as '人兽混合体'. There is some ambiguity in relation to the term '嵌合体', which has been defined to mean chimeras, but has also been used to refer to human-animal combinations in general. In relation to the HA Consultation Paper, the Chinese press used the term '嵌合体' to refer to human-animal combinations generally. The two main categories of human-animal combinations considered by the BAC have been translated by the Chinese press as '杂合体' for hybrids and '客迈拉' for chimeras. Cytoplasmic hybrid (or cybrid) embryo, which is a sub-category of hybrids, was defined as '胞质杂配胚胎'. This is consistent with the terminology used in China, notably by the Chinese Medical Doctor

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208 谢燕燕，生物道德资询委员会征询公众:你是否接受人兽嵌合体，联合早报 [Xie YY, Bioethics Advisory Committee Consults the Public: Can you accept human-animal combinations, Combined Morning Paper], 9 January 2008.

209 许翔宇， 人兽混合体? 生物道德资询委员会征询公众意见， 联合晚报 [Xu XY, Human-Animal Combinations? Bioethics Advisory Committee Seeks Public Opinion, Combined Night Paper], 8 January 2008. See also 郭秀芳与李腾宝，人兽怪研究, 引发各种问题：带人细胞的肉，你敢吃吗?，新民晚报 [Guo XF and Li TB, Human-Animal Strange Research, Raises All Kinds of Issues: Meat with Human Cells, do you dare eat?, New People's Night Paper], 8 January 2008.

Association.[210] It follows that cytoplasmic hybrids are defined as '胞质杂合体'. In some reports, a more generic term '人兽混合胚胎' is used to describe cytoplasmic hybrids as human-animal interspecies embryos. Hence a function of the HA Consultation Paper was to displace the 'old' and conventional metaphoric notions of chimeras and hybrids with ethically and scientifically 'appropriate' ones.

The approach adopted by the BAC may also be described as an analytical (or displacement) technique that sets out in taxonomies the types of chimeras and hybrids that occur naturally, those that have been created by scientists, and those that could be created.[211] Being somewhat 'natural', a recipient of blood transfusion and a mule would technically be a 'chimera' and 'hybrid' respectively, without provoking any feeling of disgust in contemporary society. Categorization based on 'natural' as opposed to 'unnatural' and further related to current and potential uses reflect (as we have discussed) Henry Greely's approach, as well as his observation that the ethical issues depend on the 'humanity', 'naturalness' and proposed uses of the chimeric organism.

2.7 Reaction of the Singaporean Public

Public consultation in Singapore on the subject of human-animal combinations concluded on 10 March 2008. Similar to previous public consultations of the BAC, written submissions were

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[210] 中国医师协会，人兽混合胚胎问世 [Chinese Medical Doctor Association, Birth of Human-Animal Hybrid Embryo], 3 April 2008. See also: 你能否接受人兽嵌合体? [Can you accept human-animal combinations?], 1 September 2008.

[211] Bioethics Advisory Committee, Singapore, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 8 January 2008, at 6. The BAC distinguished between fictitious chimeras (eg centaur) from biological ones (eg pregnant woman).

received from scientists, lay members of the public, and from institutions. In addition, 58 entries were made on the REACH Discussion Forum[212] from at least 43 individuals.[213] Most comments on REACH are made anonymously (or pseudonymously).

Written Submissions. A majority of the respondents indicated some level of support for some or all forms of human-animal combinations. The main reasons or requirements (as the case may be) given for supporting or in order to allow research involving the creation and use of human-animal combinations are: (a) No mixing of human and animal genetic materials; (b) There are legal and/or ethical regulatory systems in place; (c) Broader consultative process required; (d) Alternative technology (such as induced pluripotent stem cell technology) should be explored; (e) Clear informed consent and other procedures required; (f) Research should be clearly beneficial; and (g) Avoid over-regulation.

The main reasons for opposing the research by a minority of respondents are: (1) Moral Outrage or Repugnance; (2) Misunderstanding of what is intended; (3) Concerns about objectivity or effectiveness of regulation; (4) Challenging the effectiveness or value of the research, or highlighting its risk; (5) Arguments based on human dignity and against instrumental use of human beings; (6) Concern with maintaining the distinction between humans and animals; (7) Objections based on the moral status of the embryo; (8) 'Playing God', hubris and allowing scientific pragmatism to replace ethics; (9) Violation of the laws of Nature; and (10) 'Slippery slope' concerns.

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212 REACH (Reaching Everyone for Active Citizenry @ Home) is set by the Feedback Unit in 2006 to engage and reach out to as many Singaporean and permanent residents as possible to develop and promote an active citizenry through citizen participation and involvement.

213 Repeated entries on REACH Discussion Forum were excluded as far as practicable to avoid double-counting.

Some respondents have segregated the different types of human-animal combination whereas four other respondents have treated such combinations as effectively cytoplasmic hybrids or combinations created at the cellular level and are thereby subject to the 14-day rule. Others have addressed human-animal combinations categorically. It has also been indicated that there may be a need to relate ethical and legal discussions to particular types of human-animal combination. In addition, several respondents have called for broader representation (especially non-governmental bodies and bodies that regulate the use of animals) in the governance of the creation and use of human-animal combinations.

Consistent with the feedback from stem cell researchers, not all scientists are supportive of the creation and use of cytoplasmic hybrids due to concern over feasibility and lack of justification. Induced pluripotent stem cell technology has been welcomed by a number of respondents as a viable alternative although most respondents agree with the BAC's proposal for a multi-fronted approach.

Other members of the public are likely to be opposed to human-animal combinations if they are of the view that such combinations will not be confined to a laboratory environment or if they have religious concerns. Almost all religious bodies that have provided written responses are either opposed to or have indicated very limited support for human-animal combinations. Interestingly, the Islamic Religious Council of Singapore, an Islamic Religious organization and a professional body with some religious affiliation to Islam have indicated support for the research provided that effective regulatory safeguards are in place. However, there is some concern over the possibility of over-regulation and the lack of explicit stem cell legislation.

REACH Feedback. Of the 43 individuals who provided feedback on the REACH Discussion Forum, a majority (18) have expressed some support for research using human-animal combinations. However, a large number of individuals (12) did not express any view, whereas the number of individuals who are neutral or did not express a clear view on the issue (7 respondents) is close to the number of individuals opposed to the research (6 respondents). In addition, six comments were received via REACH on the Consultation Paper in general. Of these, 5 expressed opposition to the research.

On the whole, there was no clear indication of support or opposition for the research. A similar outcome was observed of the British public's reaction to research involving cytoplasmic hybrids. Nevertheless, the outcome of the public consultation was important to the BAC for a number of reasons. First, the absence of strong public reaction was an indication of public receptivity to the research. This may perhaps be attributed to the absence of a dominant group or discourse in the consultation. Second, there was no serious omission in the ethical identification of issues or interests. Strongest reaction for and against the research were for reasons that were within expectation. A level of agreement over ethical rules that can be applied is important for the purposes of legal objectification, as we shall consider. Third, emphasis on sound and effective regulation enabled a practical and measured response to a number of uncertainties and concerns.

2.8 Contributory Developments in the UK

The emphasis on regulation by the lay public and experts alike may at first seem surprising, but perhaps less so when viewed in context. There was considerably sensationalized reporting in the media on regulatory development in the UK on cytoplasmic hybrid embryos from the time before and extending right through the public consultation of the BAC. As a matter of public policy, developments in the UK have been highly influential in Singapore. Hence the UK's experience with this particular type of human-animal combination was instructive as to how such research could be understood as a policy concern. In the UK, human-animal combinations in research became a public issue when an expert advisory group recommended that the creation of cytoplasmic hybrid embryos should be prohibited.[214] However, the House of Lords Select Committee on stem cell research did not agree, and suggested that, on the contrary, research using a cytoplasmic hybrid embryo might be more acceptable to people given that human eggs would not be required.[215] The House of Commons Science and Technology Select Committee agreed, and proposed new legislation in 2005 to define the nature of inter-species embryos and to make their creation legal for research purposes, subject to the 14-day rule.[216] In August that year, the Science Media Centre organized a background briefing on chimeras. At this briefing, the possibility of using cytoplasmic hybrid embryos in research was discussed, and concerns over

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214 Department of Health, UK, *Stem Cell Research: Medical Progress with Responsibility*. London: Department of Health, June 2000. See Recommendation 6, at 47.

215 House of Lords Select Committee, UK, *Stem Cell Research*, 2002. See paragraph 8.18.

216 House of Commons Science and Technology Select Committee, *Reproductive Technologies and the Law*, 2005, paragraph 66.

regulatory loopholes were also raised. This was identified as the first step in what became a concerted attempt to keep public and politicians, via the media, fully informed.[217]

By December 2006, however, a government white paper proposed prohibiting the creation of hybrid and chimeric embryos.[218] This development followed from applications by researchers from King's College, London, and Newcastle University for permission to create cytoplasmic hybrid embryos for research. The possible imposition of legal limitation to embryonic stem cell research prompted the HFEA to conduct a full consultation to gauge public opinion,[219] and the pooling together of the efforts of the AMS, the Wellcome Trust, the Royal Society, the Medical Research Council, the Association of Medical Research Charities and many individual patient charities to amplify the message of possible benefits that could be gained by allowing the research. A consultation paper entitled 'Hybrids and Chimeras' was issued by the HFEA to solicit feedback over a period of three months, from 26 April to 20 July 2007.[220] Those who responded to the poll or to public consultation had strong views one way or the other. The full consultation conducted by the HFEA revealed that while up to 67% of the respondents initially opposed creating hybrids in general, the opposition fell to 30% and support rose to 50% when it was explained that the research could help scientists understand diseases such as Parkinson's and Alzheimer's disease.[221] From the various polls and public consultations conducted, it was

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217 Geoff Watts (ed). *Hype Hope and hybrids: Science, policy and media perspectives of the Human Fertilisation and Embryology Bill*, London: The Academy of Medical Sciences, Medical Research Council, Science Media Centre and Wellcome Trust, 2009, at 11.

218 Department of Health, UK, *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*. London: Department of Health, December 2006.

219 Human Fertilisation and Embryology Authority, UK, *Hybrids and Chimeras: A report on the findings of the consultation*. London: Human Fertilisation and Embryology Authority, October 2007.

220 Human Fertilisation and Embryology Authority, UK, Press Statement, 26 April 2007.

221 David A. Jones, What does the British public think about human-animal hybrid embryos? *Journal of Medical Ethics* 35, 3 (2009): 168-170, at 169.

observed that on the whole, there was not a clear majority of the British public either opposed to or supporting the research.[222] However, the polls did suggest majority public support for the creation of hybrid embryos when the likelihood of treatments for named diseases was indicated. Where there were no claims of important potential medical advance (such as in the creation of 'true' hybrids), a majority was opposed.

It was during this time that the AMS published a report on the subject of inter-species embryos,[223] to clarify the terminology and the scientific issues in the debate. The report was put together relatively quickly in view of the political developments on the subject.[224] Consultations were conducted with regulatory authorities like the HFEA. The substantive report begins with an explanation of the value of human-animal combinations in the context of hESC research and SCNT. It emphasizes that this research is directed at learning how to control stem cell differentiation and development, nuclear reprogramming and generating specialized tissues in culture or animal models.[225] Human-animal combinations could help overcome the shortage of human oocytes for such research.[226]

Strong arguments are presented for extending the current legislation on human embryo research to inter-species embryos. Under such a framework of regulatory control, the AMS indicates that there would be no substantive ethical or moral reasons not to proceed with the research on

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222 *Ibid*.

223 The Academy of Medical Sciences, UK, *Inter-species embryos: A report by the Academy of Medical Sciences.* London: Academy of Medical Sciences, June 2007.

224 Interview with Dr Helen Munn, Executive Director (then Director, Medical Science Policy), Academy of Medical Sciences, 1 April 2008.

225 The Academy of Medical Sciences, UK, *Inter-species embryos: A report by the Academy of Medical Sciences.* London: Academy of Medical Sciences, June 2007, at 7-14.

226 *Ibid*, at 16-17.

cytoplasmic hybrid, human transgenic or human chimeric embryos.[227] It further argues that *in vitro* laboratory research involving cytoplasmic hybrids or other inter-species embryos would not raise any significant safety risks over and above regular cell culture, provided that good laboratory practice is rigorously followed. However, if cell lines derived from such embryos should ever be contemplated for therapeutic use, it would be prudent to scan the mitochondria and cytoplasmic RNA of the species to be used for pathogens.[228]

The report of the AMS was a galvanizing force, and contributed to a briefing for Ministers of Parliament jointly undertaken by the AMS, the Medical Research Council, the Royal Society and the Wellcome Trust at the House of Commons on 6 May 2008. The concerted effort of scientific bodies and medical charities in the UK culminated in the successful passage of comprehensive legislation on the subject through Parliament. The HFE Act 2008 was passed in October 2008 and received the royal assent in November 2008.[229] It supersedes the 1990 version of the legislation. Of relevance to the BAC is Part 1 of the legislation, which ensures that all research on human embryos that occur outside the body, and research on human admixed embryos, where animal DNA is not predominant, are subject to strict regulation. The Act, which is administered by the HFEA, was implemented in stages, with the legislative provisions that relate to research on embryos being effective from October 2009.

In the Act, the term 'embryo' means a live human embryo and includes "an egg that is in the process of fertilization or is undergoing any other process capable of resulting in an embryo",[230] and a 'human admixed' embryo is specifically defined.[231]

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227 *Ibid*, at 30-31.
228 *Ibid*, at 38.
229 Human Fertilisation and Embryology Act, UK, 2008. See also Explanatory Notes to the legislation.
230 *Ibid*, Section 1(2).

Reference to human cells or animal cells means either cells from a human or human embryo, or cells from an animal or animal embryo, as the case may be. Thus human admixed embryos, which are created from a combination of human and animal genetic material, would include:

1. Human cytoplasmic hybrid embryos;
2. True human-animal hybrid embryos;
3. Transgenic human embryos;
4. Human-animal chimeric embryos; and
5. Any other embryo that has human and animal nuclear or mitochondrial DNA, but in which the animal DNA is not predominant.

The creation and use of human-admixed embryos covered under the legislation is allowed under license if they are purely for laboratory research, and such research should not extend beyond 14 days of embryonic development. These embryos are to be destroyed after the 14-day limit is reached.[232] The Act also stipulates that a license cannot authorize placing a human admixed embryo in a woman[233] or in an animal.[234] In addition, the Act does not cover the creation or use of animal chimeric fetuses or animals, or (as indicated above) the creation or use of human admixed embryos in which animal DNA is predominant.

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231 *Ibid*, Section 4A (6).
232 *Ibid*. Sections 4A (2) and 4A (3).
233 *Ibid*. Section 4A (1) (a).
234 *Ibid*. Section 4A (4).

2.9 Report on Human-Animal Combinations

With the conclusion of the public consultation and with positive regulatory developments in the UK, a draft set of recommendations were prepared by the HECR Working Group. The substance of these recommendations was heavily influenced by the framework laid out by the NAS and the ISSCR (to be discussed further in the next Chapter), legislative change and related developments in the UK, and local feedback. The recommendations were focused for a time on addressing the creation and use of pluripotent cells in general, but it reverted to specific focus on human-animal combinations after discussion continued at the level of the BAC.[235] This approach was felt to be expedient for three main reasons. First, the scientific community was concerned that an overly prescriptive treatment of all conceivable type of human-animal combinations could burden research. This (as we have discussed) appeared to also have been the view of NACLAR. By limiting recommendations to the most controversial of human-animal combinations, there would be a clear signal to all concerned that a majority of the research involving such constructs is not considered to be ethically contentious. Second, feedback from the National Council of Churches in Singapore (NCCS) and the Catholic Medical Guild (CMG) made clear an expectation that the BAC was to respond to their specific ethical positions and contentions.[236] This message was reiterated when the BAC met with religious group leaders. Dr Roland Chia, Dean of Postgraduate Studies at a theological college in Singapore and a representative of the NCCS,

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[235] Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010. The BAC explicitly sets out (at paragraph 1.7, at 5-6) the two types of human-animal combinations that are considered in the HA Report as animal chimeras (in which human pluripotent cells have been introduced at various stages of the animal's development) and cytoplasmic hybrid embryos. It further states (at paragraph 1.8, at 6) that the HA Report "does not extend to consideration of…other more speculative combinations."

[236] The NCCS indicates in its feedback to the BAC that: "[w]hile the consultation paper is very lucid and tightly argued, at the same time it suffers the disadvantage of being too general. Because there are many different types of chimera research, it is not only profitable but it is indeed necessary to evaluate the ethics of each. Only when this is done will a clearer and fairer picture emerge." *Ibid*, at C9-2.

plainly stated his dissatisfaction with the BAC's generic ethical arguments; a view supported by the CMG.[237] In response to this critique, the Secretariat prepared a point-for-point rebuttal of ethical arguments raised by the NCCS and CMG, but a watered-down (although still more focused) version was ultimately published in the HA Report.[238] This need to add focus to the ethical discussion was another reason for limiting the scope of the HA Report to particular human-animal combinations. Third, a narrower scope was considered to more effectively direct public and regulatory attention to the 'pertinent issues'. Even then, the HA Report was only published towards the end of 2010, even though the recommendations were finalized and presented to the SCLS at the end of 2009.[239] This delay was agreed to by the BAC after regulators have requested for more 'reaction time', especially since a recommendation of the BAC was for a single national body to be established to review and monitor all stem cell research involving human pluripotent stem cells or human-animal combinations conducted in Singapore.[240] The regulation of stem cell research *per se* was unlikely to have been the cause of the delay since a similar recommendation was in fact advanced earlier. The SC Report recommended that there should be a statutory body to license, control and monitor all stem cell research conducted in Singapore, together with a comprehensive legislative framework and guidelines.[241] However, a more direct form of control has not been instituted, perhaps owing to preference for a 'phased' or incremental regulatory approach, and to the fact that stem cell

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237 Fieldnotes, 13 August 2008.

238 Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, pp 16-19. In particular, the ethical contention of 'Playing God' has been explicitly addressed in the report (at p 18), whereas this was only alluded to in the HA Consultation Paper.

239 Fieldnotes, 20 November 2009.

240 Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at 3.

241 Bioethics Advisory Committee, ***Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*. Singapore: Bioethics Advisory Committee, June** 2002, Recommendation 8, at viii.

research did not have the volume or scale that justified intense regulatory attention. Hence, the more likely reason was the ambiguity as to which government agency should shoulder the regulatory burden, since different agencies were responsible for overseeing basic research as opposed to clinical trials, and human as opposed to animal research.[242] In other words, there was a problem with regulatory categories. Another reason was to allow more time to observe developments in the UK following legislative changes introduced at the end of 2008.

Consequently, the HA Report is relatively concise, comprising only five recommendations, although bearing the generic title of 'human-animal combinations'. Of these, one recommendation is directed at cytoplasmic hybrid embryos, and another two relate to (human-to-animal) chimeras (which, as we have earlier noted, exclude animal-to-human chimeras). Together, these recommendations make clear the types of research that are permitted.

In order to include human-animal combinations within the rubric of the ethics framework, the regulated methods of deriving new stem cell lines have been enlarged to include newer methods such as parthenogenesis, reproductive semi-cloning, altered nuclear transfer, and inter-species SCNT. In addition, research involving the creation of chimeric animals through the introduction of human embryonic stem cells into non-human animals at any stage of embryonic, fetal, or postnatal development have also been brought within the framework. Consistent with the positions of key policy bodies, the BAC makes clear that animals into which any kind of

[242] An observation to this effect was made in the HA Report: "Currently, no governmental body in Singapore has explicit statutory power to regulate human stem cell research involving human-animal combinations." Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, paragraph 4.9, at 22.

pluripotent cells are introduced should not be allowed to breed.[243] For animals into which whole human embryonic stem cells had been introduced, a concern was that if such animals were allowed to breed, human gametes could be produced by chance, so that a substantial amount of human materials would be present in the next generation. While it is unlikely that such animals will reveal human features, the possibility remains. However, such a risk will not arise for transgenic animals, where only a very small quantity of human genes is incorporated.[244]

2.10 Chimeras and Hybrids as Regulatory Objects

In her contribution to the legal section of the European Union's Chimbrids project, Elisabeth Rynning observes that a difficulty in regulating chimeras and hybrids is the lack of knowledge regarding the potential future value and the risks involved. Consequently, "the necessary balancing of interests to a certain extent will amount to a balancing of two unknowns, making it virtually impossible to reach any well-founded conclusions on proportionality."[245] In managing this uncertainty, categorization has the effect of lowering the informational deficiency by streamlining a social phenomenon on the basis of certain desired information qualities. Social and cognitive psychologists tell us that this is how we – as human beings – generally store and process information.[246] The generation of categories through rationalization and systematization

243 *Ibid*, Recommendation 4, at 3.

244 The BAC suggests that research involving certain types of transgenic animals (such as transgenic non-human primates) can be ethically contentions. Such animals could be the subject of another report to be produced by the BAC. *Ibid*, paragraph 1.8, at 6.

245 Elizabeth Rynning. Legal tools and strategies for the regulation of chimbrids, In J. Taupitz and M Weschka (eds), *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009, pp 79-87, at 85.

246 Judith A. Howard, Social Psychology of Identities, *Annual Review of Sociology* (2000) 26: 367-393.

in legal and regulatory processes does not detract significantly from our basic cognitive orientation. Reductionism in categorization is evident in what Bruno Latour describes as involution in terms of a model of qualification as opposed to fictionalization.[247] Latour argues that "[w]hereas in science everything is done to ensure that the impact of new information upon a body of established knowledge is as devastating as possible, in law things are arranged in such a way as to ensure that the particular facts are just the external occasion for a change which alters only the law itself, and not the particular facts, about which one can learn nothing further, beyond the name of the claimant."[248] In this connection, Alain Pottage observes that an inquiry into the facts in the case of law "is confined to the question whether the facts are such as to trigger the application of the rule…this is a mode of involution rather than just a mode of classification because qualification is less about cognition than it is about steering institutional action."[249]

The tabularized survey of a range of human-animal combinations based on certain scientific, ethical and social criteria (in Table 2) is an attempt at acquiring an understanding of the subject at hand for the purposes of steering institutional action. With understanding, it becomes possible to appreciate the regulatory risk[250] entailed as knowledge enables control. Hence categorization through typifying human-animal combinations is also an exercise in the enumeration of risks entailed. Reification through objectification was also thereby achieved through the substitution

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247 Bruno Latour, Scientific Objects and Legal Objectivity. In Alain Pottage and Martha Mundy (eds), *Law, Anthropology, and the Constitution of the Social: Making Persons and Things*. Cambridge: Cambridge University Press, 2004, pp 73-114, at 104.

248 *Ibid*, at 105.

249 Alain Pottage, Introduction: The Fabrication of Persons and Things. In Alain Pottage and Martha Mundy (eds), *Law, Anthropology, and the Constitution of the Social: Making Persons and Things*. Cambridge: Cambridge University Press, 2004, pp 1-39, at 21-2.

250 Regulatory risk relates to the risk of not achieving the regulatory objectives or the risk of generating other regulatory issues that are unanticipated when regulation was introduced. See Cass Sunstein, Health-Health Tradeoffs. In Cass Sunstein (ed), *Risk and Reason*. Cambridge: Cambridge University Press, 2002, pp 133-152.

of scientific, ethical and social content in a categorical manner for mythical ones in the metaphors of 'chimeras' and 'hybrids'. As earlier considered, the displacement technique may give description to the BAC's approach in the HA Consultation Paper. Models *for* 'chimeras' and 'hybrids' were constructed to replace models *of* these constructs. The elimination of categories that followed, from the many combinations down to human-to-animal chimeras and cytoplasmic hybrid embryos effectively reduces the uncertainty in and regulatory risks of the subject matter, and this facilitates control, as well as action.

The involution that one observes in the BAC's deployment of scientific and ethical (or regulatory) categories to objectify a particular metaphorical content for (or viewpoint of) hybrids and chimeras is not dissimilar to the way in which factual 'objectivity' is generated through science. Objectification enables reification, so that hybrids and chimeras are no longer images of endless adverse outcomes, but are objects that could be brought under some form of institutional control. In this sense, reification renders calculability and enables institutional action. In addition, a sense of 'found-ness' through the erasure of context and association with perceptions of 'natural-ness' confer legitimacy on this otherwise limited content or viewpoint. The largely positive public reaction to the BAC's recommendations suggests that the BAC has been relatively successful in re-constituting conventional metaphors of hybrids and chimeras as freestanding legal objects of chimeras and hybrids that could fall under the power of regulatory control. We proceed to consider further how this sense of institutional control could arise.

2.11 Metaphors that Arrest the Slide Downwards

Philosopher and BAC member, Professor Anh Tuan Nuyen, commenced his segment of the public lecture on 16 August 2008 with a travesty of the 'slippery slope' argument.[251] He narrated a scene with two men chatting in a pub. One man told the other that he intends to emigrate. When asked for the reason, he said that homosexuality was initially illegal in the country. The government recently decided to repeal the prohibitive legislation and may even decide to allow same-sex marriage. He surmised that given these developments, he should leave the country before he is forced to be gay in the not too distant future.[252] From this vantage point, the flaw in reasoning is apparent. Yet, the metaphorical argument of 'slippery slope' has been raised in each and every public consultation conducted by the BAC. Feedback from the public consultation also indicates the persuasiveness of this argument in the mind of the public. And this phenomenon is by no means confined to Singapore. Dag Stenvoll provides illustrations of the extensive deployment of this argument in the Norwegian parliamentary debates on sexuality, abortion and new reproductive technologies from the 1950s through the 1990s. His analysis of the 'slippery slope' mechanics is instructive:[253]

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[251] The public forum entitled 'Mixing human and animal tissues: Is such research ethical?' comprised three speakers: a stem cell scientist (Professor Lawrence Stanton), a philosopher (Professor Anh Tuan Nuyen) and a medical ethicist (Professor Bernard Lo). In a newspaper article that publicised this event, it was observed that: "Opponents fear that tinkering with the human genome puts science on the slippery slope to creating animal-human hybrids". The BAC's position was then indicated as: "But unlike Hollywood science, researchers are not looking to create half-man half-animal monstrosities…" See Tania Tan, Forum on ethics of mixing human, animal genes, *The Straits Times*, 14 August 2008.

[252] Certain homosexual conducts are technically illegal in Singapore and could constitute a criminal offence. At around the time of the public lecture, there has been ongoing debate as to whether this Edwardian legacy should be repealed. In order to pacify a vocal conservative minority, the government has adopted a pragmatic position of retaining the legislation, but providing an assurance that this legislation will not be enforced.

[253] Dag Stenvoll. Slippery slopes in political discourse. In Terrell Carver and Jernej Pikalo (eds), *Political Language and Metaphor: Interpreting and changing the world*. London and New York: Routledge, 2008, pp 28-40, at 29. Stenvoll observes (at 37) that metaphors are significant in politics because they have constitutive functions in that they contribute to the scene that set of a sequence that inevitably ends in tragedy.

> The slippery slope image works metaphorically in at least two ways. First, it sets up the physical world of solid objects as an analogy to political matters, implying that politices is like the physical world: if you 'move' something in the world of politics, like making or changing a particular law or policy, other things will inevitably follow…Second, the slippery slope does in itself entail a particular image of movement: from a good or relatively good place to a relatively worse or natural world of determinism and laws of physics. It imposes a kind of unidirectional, unstoppable movement which, when used metaphorically about politics, binds phenomena together in a specific way…The metaphorical expression of a slippery slope also involves a dual displacement of focus: regarding time perspective, from the present to the future, and regarding problematisation, from the instant to the danger case.

When applied in ethical debates, the determinism in Stenvoll's 'POLITICS IS PHYSICS' is no less forceful as 'ETHICS IS PHYSICS'. It became a subject for critique in the editorial of an issue of the *Journal of Medical Ethics*.[254] Whether a scientific possibility is seen as 'a slope going down' towards some detriment or an escalator going up towards some benefit is ultimately a prediction. This misleading metaphoric stealth of hand led to the BAC's decision to avoid using the phrase 'slippery slope'. Focus should instead be directed at the avoidance of adverse outcomes through means such as regulation, and on remedies should such outcomes materialize.

Of pertinence is the ethnographic finding of Sarah Franklin and Celia Roberts on the uptake of embryo research and new reproductive technologies in the UK. Contrary to the view of PGD as a

[254] Soren Holm and T. Takala. High hopes and automatic escalators: a critique of some new arguments in bioethics, *Journal of Medical Ethics* (2007) 33, 1: 1-4.

socially destabilizing technology in offering 'too much choice', their study suggests a much more careful and thoughtful engagement with the difficulties presented by PGD.[255] In the light of this, the BAC considers effective regulation to be a means by which the determinism entailed in the 'slippery slope' argument could be countered.[256]

In the BAC's HA Report, the metaphors of 'hybrid' and 'chimera' could be broadly regarded as 'world-perceiving', in that they present conceptual frameworks of understanding that influence our perception of the world.[257] As we have seen, the minimum content of these metaphors are directed at displacing particular cultural mindsets that range from the fear of bringing to life mythical creatures to religious concerns over transgressing 'natural' boundaries. Their production is directed as reifying particular scientific and ethical notions in a way that not only enables institutional action (particularly regulatory control), but also the consumption or exploitation of particular biological constructs in scientific work. For instance, the creation and use of a cytoplasmic hybrid embryo would not have found support in prevailing cultural (and especially those of the Judeo-Christian traditions) beliefs. This is broadly speaking the context to the metaphors of 'hybrid' and 'chimera' in the HA Report. We have also seen the range of formats that the BAC has deployed, which include analytical tables, schematic diagrams, artistic portrait (even if limited to the level of the Secretariat) and comparative tables (to be further discussed in Chapter 4). Putting these constructed metaphorical models through public consultation secures for them a degree of legitimacy, so that they become not only models of

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255 *Ibid*.

256 Bioethics Advisory Committee, Singapore, *Human-Animal Combinations for Biomedical Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 8 January 2008, paragraph 60 at 29.

257 Aside from 'world-perceiving', James Underhill indicates that metaphors could also be 'world-conceiving' (which we will further discuss in the next Chapter), and could relate to a cultural mindset, personal world or otherwise a perspective. James W. Underhill, *Creating Worldviews: Metaphors, Ideology and Language*. Edinburgh: Edinburgh University Press, 2011, at 7.

'seeing-as', but also models of social (and ideological) mediation and consensus.[258] The BAC attempted to communicate this in the HA Report when it indicated that the faith of the Singaporean public in the regulatory approach was consistent with relatively concurrent developments in leading jurisdictions.[259] However, to say that 'hybrid' and 'chimera' are metaphors is an incomplete account, especially since the term 'metaphor' suggests a relatively well settled lexical content or meaning. In the next section, it is argued that Annelise Riles's analytic of a placeholder provides a more rigorous account.

2.12 Scripting Metaphors as Placeholders

Annelise Riles argues that collateral put up as security by a party to a financial swap transaction could be understood as a 'placeholder', which is "a device for governing the near future".[260] As a legal technique, it serves as "a tool for producing working truths, for the moment".[261] As for its substantive character, it could be understood as a kind of legal fiction, such as the notion that a

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258 Particularly where scientific models are concerned, they are means of theory construction, exploration, representation, measurement and learning, through a process that could be understood as incremental and pragmatically consensual. See Margaret Morrison and Mary S. Morgan, Models as mediating instruments. In Mary S. Morgan and Margaret Morrison (eds), *Models as Mediators: Perspectives on Natural and Social Science*. Cambridge: Cambridge University Press, 1999, pp 10-37.

259 Bioethics Advisory Committee, Singapore, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at 20-22.

260 Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 180. In the context of her research, a placeholder is understood as (at 169) "in the meantime, that is, for the near future, the parties simply agree to act as if the holder of the collateral (the pledgee) already has clear and complete rights over the collateral (as if the parties are no longer trapped in the messy "meantime")."

261 *Ibid*.

corporation is a person. It is an "As If", or a consciously false statement that is irrefutable. Riles provides this explanation:[262]

> When I say that legal fictions are technicalities or techniques of private law, therefore, I mean that they are *nonrepresentational*…Thus the legal fiction is not really so much an epistemological claim as it is a special kind of pause, for the moment. In mathematics, a placeholder is a "symbol, frequently an empty box, used in teaching to denote a missing quantity or operator in an expression." One creates a placeholder in order provisionally to overlook it. In other words, it is a technique for working with and in the meantime. As such it has no particular content or meaning, except that it defines and manages the near future – the time for which this particular commitment holds true. But it is also a political device, a kind of collective commitment: The original meaning of the term was overtly political …

Elsewhere, Riles explains that unlike other kinds of legal fiction, a 'placeholder' emphasizes an often overlooked temporal dimension (or "for the time being-ness"):[263]

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[262] *Ibid*, at 173-174 (Emphasis in original). In a different forum, Riles indicates: "One creates a placeholder in order to overlook it for the moment. In other words, it is a technique for working with and in the meantime. As such, it has no particular content or meaning, except that it defines and manages the near future, the time for which this particular commitment holds true. But it is also a political device, a kind of collective commitment…the placeholder's central feature is that it forecloses the question of the moment for the near future, but by resolving it, but by papering over it…by creating a dummy solution subject to future reevaluation. The placeholder is the precise opposite, then, of pragmatist ways of thinking about the ambiguity or open-endedness of the present as an open zone of endless possibility and unpredictability." See Annelise Riles. Collateral Expertise: Legal Knowledge in the Global Financial Markets. *Current Anthropology* (2010) 51, 6: 795-818, at 803.

[263] *Ibid*, at 815 (Emphasis in original).

> It is not that things are unsettled, not that we need to direct our attention to further inquiry (probabilities); it is just that they are settled only *for the time being*. It will be up to future actors to decide what is the state of affairs at that time.

Temporality encapsulated in the notion of 'placeholder' is critical to appreciate fully the significance of metaphors in a policy environment. It is incomplete to think of 'chimera' and 'hybrid' only as models for 'seeing as'. When the endeavor was initiated to give meaning to such biological constructs by transposing the question of identities from the scientific to ethical domain, the models of scientific 'Seeing As' became models for 'Seeing As If'. In a sense, the transformation also reflects a movement from *is* to *ought*; from scientific facticity to a normative one. The 'papering over' was by way of a temporal truism that displaced the multiplicity of meanings over material constructs. Put differently, it was a temporal and purpose-specific semiotic superstructure (a *lingua franca* perhaps?) layered over a variedly composed material-semiotic substrate.[264] Many researchers and policy-makers continue to see this endeavor as one part durable (material) and one part temporal (semiotic). In the meeting with scientists, we find that many of them appeared to have their own classificatory scheme. Again, this is not a phenomenon that is confined to Singapore. Shortly after I started my fieldwork, Professor Martin Bobrow (who was in Singapore for a meeting) shared over dinner that scientists in the UK have adopted different definitions of chimeras and hybrids, making it necessary for the AMS and allied organizations to push for standardized meanings.[265] As we have seen, the situation was no less different in Singapore. At the BAC's meeting with scientists, chimeras routinely created in

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[264] Annelise Riles observation that placeholder is a material, sociotechnical phenomenon, not simply a concept is relevant here. See Annelise Riles. *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 175.

[265] Fieldnotes, 25 September 2007.

the course of research was not a problematic that fell within the definition of human-animal combinations. Prior to the meeting, many of them considered human-animal combinations to relate only to cytoplasmic hybrid embryos. In contrast, the NCCS indicated that the BAC did not go far enough in analyzing the ethical implication of the full spectrum of chimeras and hybrids that could be created. This is a fair observation because the 'placeholders' could render other accounts of human-animal combinations 'invisible' by simply not giving recognition to them.

As placeholders, 'hybrids' and 'chimeras' thereby served (in the words of Riles) as political devices that foreclose the many unanswered questions of the moment for the near future by creating a dummy solution subject to future reevaluation. Being devices for 'Seeing As-If', it is not the intent of the BAC to resolve more philosophical issues relating to the essence of human beings and animals through these re-constituted metaphors. A 'hybrid' in the HA Report is narrowly construed as referring to cytoplasmic hybrid, and in research, it is treated *as-if* it is a human embryo, so that the research must not extend "beyond 14 days or the appearance of the primitive streak, whichever is earlier, nor be implanted into any human or animal uterus."[266] In this way, the thorny issue of when human life begins is side-stepped, and taken to be irrelevant to the situation at hand and for the time being. As for chimeras, the requirements of avoiding the "creation of entities in which human sentience or consciousness might be expected to occur",[267] as well as precluding such chimeric animals from breeding,[268] enable a *seeing as-if* there is no breach to the human versus non-human divide. Even if human pluripotent stem cells have been introduced into non-human animals, these chimeras remain animals and continue to be treated as

[266] Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at 3, Recommendation 2.
[267] *Ibid*, Recommendation 3.
[268] *Ibid*, Recommendation 4.

such, apart from precluding their procreation. The HA Report further creates a sense of regulatory control (as we have discussed) and a notion of free choice, in refusing to engage in research involving hybrids and chimeras on the ground of "conscientious objection".[269] Hence, while the HA Report may purport to address human-animal combinations generally, it is in effect an embodiment of pockets of information in a well-defined (storage) space – resources that could be drawn upon for specific (mainly scientific, ethical and policy) purposes. Not surprisingly, a number of ambiguities remain. It is still not entirely clear if non-human stem cell may be introduced into a human embryo or fetus, or if 'true' hybrids may be created by mixing human and non-human gametes. In addition, the question of how human sentience could be defined and measured has been left unanswered. There is only a general assurance that *for the time being* a non-human animal with human sentience is unlikely to be produced.

2.13 Explicating Context

When constituted as regulatory objects (and subjects), chimeras and hybrids fall under the power of regulatory control. Earlier on, policy-makers discovered that the construction of the ethico-legal category of the 'pre-embryo'[270] is a means by which human embryo research could be kept off the slippery slope. Arguably, the ability to control 'pre-embryos' as 'things' underscored Dame Warnock's confidence in a legislative response to human embryo research.[271] As we have also seen, the distinction drawn between research and therapy, the segregation of motives and the

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269 *Ibid*, Recommendation 5.

270 That is, an 'embryo' from the point of creation up to time the primitive streak appears – which is approximately 14 days for a human embryo.

271 Michael Mulkay. *The Embryo Research Debate: Science and the Politics of Reproduction*. Cambridge: Cambridge University Press, 1997, at 149.

requirement of informed consent could all be regarded as ethical and legal 'technologies' by which the object of 'pre-embryo' is carved out of the social bedrock.[272] Although reification may present placeholders like 'pre-embryo', 'hybrid' and 'chimera' to be somewhat free-standing, the techniques deployed by the BAC in their construction reveal that they are deeply embedded in particular scientific, ethico-legal and political discourses.

Mariana Valverde illustrates the importance of context (or the broader social bedrock) in showing the various ways in which film, television and newspapers create unrealistic views of crime and crime control in the minds of the public.[273] Media representations of courtrooms, police departments, prisons and people who populate them must be understood to have an impact on how certain evidence is received and interpreted. More important for present purposes is her observation that signs, meanings and myths are integral components to all social processes, including to those relating to crime and justice.[274] Citing Ferdinand de Saussure, she indicates that meaning is not inherent in words or other signs, but emerges through differentiation from competing signs, as well as association with similar signs. Hence creation of meaning requires system-wide relations of contrast and comparison.[275] She further indicates that Freudian metonymy (or displacement) and metaphors are ways in which associations are made or unmade. Apart from signs, myths also make representations and have meaning. She notes:[276]

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272 The continued use of these 'technologies' in the shaping of human eggs is considered in Chapter 5.

273 Mariana Valverde, *Law and Order: Images, Meanings, Myths*. New Brunswick: Rutgers University Press, 2006.

274 *Ibid*, at 163.

275 *Ibid*, at 20-21.

276 *Ibid*, at 25.

> A myth...is not a lie or a misrepresentation. It is not the opposite of 'truth'. In fact, myths are often conveyed by representations that are not manipulated, tampered with, or posed. There are few myths more powerful than the generic 'happy childhood' that is the common denominator of most baby photos, for instance. And yet the parents are hardly engaging in a conspiracy to disseminate the patriarchal ideology of the nuclear family when they proudly show their relatives pictures of little Jane. The point is that mythical meanings get communicated, sometimes very purposefully but at other times unwittingly or even accidentally, through certain representations whose meanings are not within the control of the person taking the photo or writing the words.

Valverde further observes that semiotic analysis requires one to consider content, format and context.[277] Content analysis consists of noting who was featured and who was not featured, and what kinds of crimes and criminal were newsworthy or not. It usually resists attempts to reduce it to factual information since it is often representations made by a specific author for a specific audience, and is thus embedded in particular political and cultural relations.[278] Context analysis has two dimensions: the context of production and the context of reception or consumption.[279] Format refers to particular ways of representation, such as maps used by the military, graphs by economists and diagrams of the crime scene by lawyers. These visual techniques changes the perception of audiences, especially in communicating a certain sense of objectivity in the representation made.[280]

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277 *Ibid*, at 28.
278 *Ibid*, at 35.
279 *Ibid*, at 56.
280 *Ibid*, at 51-52; 55.

In this Chapter, we have considered the ways in which legal techniques have been used to construct chimeras and hybrids as regulatory 'objects' (and subjects). These techniques include not only distinguishing between medical therapy and research, but also among different types of research, such as the exclusion of transgenic animals and animal-animal hybrids and chimeras. The avoidance of terms like 'inter-species' is illustrative. Legal and ethical analytics and rules have been applied, on an almost symmetrical basis, to achieve objectification. Timing and the manner of presentation have been integral to the process, along with certain legal and ethical values. Of these, the value of fairness (or impartiality) has been one of the most important. As re-constituted metaphorical placeholders, 'hybrids' and 'chimeras' serve as models of 'Seeing As-If' that enable regulatory control. They are metaphorical for their 'world-conceiving' characteristic.[281] However, it is their temporality and 'open-texture' feature that allows the designation of conceptual frameworks which enable us to communicate with others and engage in the discussion of ideas, impressions and feelings.[282] Although tentative in construct, they are useful as 'pockets' (rather than as some pervasive discourse) of resources that have currency for the time being to achieve more immediate objectives. Even then, we must be mindful that placeholders are no less embedded in a broader context. The chapter that follows explicates this 'context' in the BAC documents, not as a broad and coherent discourse, but as interlocking and sometimes disparate globalized discourses.

[281] James W. Underhill. *Creating Worldviews: Metaphor, Ideology and Language*. Edinburgh: Edinburg University Press, 2011, at 7.

[282] H.L.A. Hart, *The Concept of Law*. Oxford: Clarendon Press, 1994 [1961], at 127-8.

CHAPTER 3

GLOBAL SCRIPTING AND

INSTITUTIONAL TECHNOLOGY OF DOCUMENTS

Abstract

Placeholders are not free-floating, but are embedded within one or more contexts or scripts. Chimeras and hybrids similarly subsist within a script composed by the BAC through drawing of linkages among different 'local' scripts using 'focal points' as anchoring references, and sustained by a generic 'common good' normative force. Scripts are in turn encapsulated within (and across) institutions and also in the documents they create. With focus on the regulatory aspects of the script and scripting processes, it is argued that the linkages foster relationalities. As an account of legal globalization, they are not as: (1) overpowering as Watson's legal transplantation, (2) rigid as Latour's circulating references, (3) programmatic as the recursive cycles of Halliday and Carruthers, or (4) structured as assemblage à la Ong and Collier. These linkages shape associations in the limited anthropology they advance. This anthropology can be crystallized into three essential features: human cognitive capabilities, human form and reproduction. In addition, this study finds that documents have an important role in the forming of linkages, as 'script-carriers', especially since they bear the essentialized component(s) of their originating institutions.

3.1 Introduction

Yan Thomas describes a mechanism deployed by Roman law in constituting *res religiosae* – matters of religious law. Under the *lex Iulia* on public violence, it is an offence to violate a sepulcher.[283] However, an empty tomb is not protected under the law unless it qualifies as a *sepulchrum*. By law, a tomb becomes a sepulchrum only after a body (or a legally sanctioned representative of it, such as a wax molding)[284] has been laid within.[285] Once a *sepulchrum*, it is a *res religiosae*, so that the particular area of the soil and the monument built upon it could not be sold, subjected to servitude, claimed as private property, acquired by prescription, used as a basis of a guarantee, seized as security or made the subject matter of a stipulation.[286] By virtue of its inalienability, rules were developed for the definition of space and body, and to confer on them transformative power.[287]

In the previous Chapter, we considered how scientific and normative rules have been deployed in objectifying material constructs (ie hybrids and chimeras) as corporeal things. Objectification is a dynamic process, as the rules of engagement do not have the immanency of perpetuity, but have varying degrees of durability. For instance, the rules of science, as the scallops of St Brieuc Bay in Callon's study demonstrates,[288] do not necessarily succeed in co-opting these biological constructs into designated roles. Similarly, normative rules depend on a larger narrative or script

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283 Yan Thomas, *Res Religiosae*: on the categories of religion and commerce in Roman law. In Alain Pottage and Martha Mundy (eds), *Law, Anthropology, and the Constitution of the Social: Making Persons and Things*. Cambridge: Cambridge University Press, 2004, pp 40-72, at 58.

284 *Ibid*, at 50.

285 *Ibid*, at 46.

286 *Ibid*, at 41-42.

287 *Ibid*, at 56 and 66.

288 Michel Callon, Some Elements of a Sociology of Translation: Domestication of Scallops and the Fishermen of St. Brieuc Bay. In John Law (ed.), *Power, Action and Belief: A New Sociology of Knowledge?* London: Routledge & Kegan Paul, 1986, pp 196-229.

for coherence, as well as support from different levels of social associations (from institutions to individuals) and goals for legitimacy and existential currency. It has been argued that temporality, historicity and epistemic flux make 'placeholder' a better description of these constructs than 'metaphor'.

In this Chapter, we consider the 'context' within which hybrids and chimeras are embedded, and how this context has been produced, received and consumed. Most evident is that it has a global character and a relatively distinct content. The concept of globalization is (at least in the US and possibly Singapore) the discursive framing of change that arguably took root "as a political-economic construct promoted mainly by financial actors and institutions, with the idea of the free market at its center".[289] Broadly speaking, literature on globalization has focused on the degree of convergence among institutions in the global environment,[290] and on various conceptualizations of institutional dynamics.[291] Given the diversity in discursive actors and interests, this discursive framing cannot be explained by the structural changes in the economy alone. Especially in the decades since the Second World War, increased international flow of goods, services, capital, data and cultural products has profoundly shaped the knowledge of our

[289] Peer C Fiss and Paul M Hirsch, The Discourse of Globalization: Framing and Sensemaking of an Emerging Concept, *American Sociological Review* (2005) 70, 1: 29-52, at 47.

[290] Some have argued that transnational corporations have contributed to institutional homogeneity, whereas others argue that there is greater heterogeneity due to the influence of local factors. On the former, see for instance: Kalman Applbaum, Educating for global mental health. In Adriana Petryna , Andrew Lakoff and Arthur Kleinman (eds), *Global Pharmaceuticals*. Durham: Duke University Press, 2006, pp 85-110; Leslie Sklair, Competing conceptions of globalization. In Christopher Chase-Dunn and Salvatore J Babones, *Global Social Change: Historical and Comparative Perspectives*. Baltimore: Johns Hopkins University Press, 2006, pp 59-78; Margaret Abraham, Globalization and the Call Center Industry, *International Sociology* (2008) 23, 2: 197-210. As for the latter, see for instance: Adriana Petryna, Globalizing human subjects research. In Adriana Petryna, Andrew Lakoff and Arthur Kleinman (eds), *Global Pharmaceuticals*. Durham: Duke University Press, 2006, pp 33-60.

[291] See for instance: John W Meyer, Globalization: Sources and effects on national states and societies. *International Sociology* (2000) 15, 2: 233-248; Jae-Mahn Shim, Gerard Bodeker and Gemma Burford, Institutional heterogeneity in globalization: Co-development of western-allopathic medicine and traditional-alternative medicine, *International Sociology* (2011) 26, 6: 769-788.

social environment.[292] Here, we consider other forces and factors that framed discussions and deliberations on hybrids and chimeras across borders. We also attempt to focus on the contribution of law (and lawyers) to the epistemological construction and governance of these biological constructs, much in the way that other studies have considered similar contributions to sociopolitical phenomena, such as the production of Europe.[293]

I propose the emergence of a global script or form, with mixed epistemological qualities of revolutions, rivalries and co-operations, mirroring the three main accounts of the institutional life of scientific knowledge. Relating to the literature on globalization, I advance four observations about the global script. First, the 'global' script arose out of events that were essentially local. Analyzing the development of stem cell policies from the standpoint of the BAC, the key triggering event that led to the formalization of guidelines for embryonic stem cell research could be traced to then US President George W Bush's decision to stop federal funding of such research. Second, the normative content of the global script is not merely drawn from one 'local' script, but several. As there are important differences among the various 'local' scripts, the 'global' script could be seen as broadly overlapping consensus of ethical and policy positions rooted in distinct and possibly incommensurable conditions, ideologies and goals. Consequently, the 'global' script is itself an incomplete account and carries, in a number of instances, inconsistencies and contradictions that in turn add to its own discursive dynamism. Third, the 'global' script draws on a number of other local and transnational scripts, especially those

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292 David Held and Anthony McGrew (eds), *Global Transformations Reader: An Introduction to the Globalization Debate*. Cambridge: Polity, 2003 (2nd ed). See especially Table 1 (at 38), which summarizes the key contentions between globalists and sceptics.

293 Take for instance a collection of papers edited by Antonin Cohen and Antoine Vauchez that considered the formation of a specific and specialized set of European institutions and relations, drawing broadly on the idea of law as a science of supranational government. Antonin Cohen and Antoine Vauchez. Introduction: Law, Lawyers, and Transnational Politics in the Production of Europe, *Law and Social Inquiry* (2007) 32, 1: 75-82, at 77.

relating to notions of the ‘common good’ and ‘dignity’, among others. Finally, it reflects different relationships (and relationalities) among states and international organizations that cannot be adequately accounted for by a single dominant discourse on globalization, be it imperialism, transplantation or assemblage. Arguably, the relationships entailed in the ‘global’ script have been more participatory than directive, and the relationalities more subtle.

We first consider the creation of a ‘local’ script in the guidelines for stem cell research issued by the NAS. This script was endorsed, with some important qualifications, by the State of California, and could be taken together as the US script. It acquired transnational influence when it was substantively adopted by the ISSCR. The US script (and its internationalized version) has been influential on the AMS, which was instrumental in steering the policy direction of the UK government on the subject, including the incorporation of critical changes to the legislative framework on some aspects of stem cell research. These changes in the UK could be surmised as another ‘local’ script that has parallel but different concerns from those of the US. Separately, the DCE and the EU generated their own scripts on hybrids and chimeras in stem cell research. The US and UK scripts were considered, but did not otherwise have pervasive influence. Nevertheless, the deliberative outcomes of the DCE and the special project group of the EU did not significantly differ from those of the US and UK. In the deliberation of the BAC, the commonalities in the various ‘local’ scripts could be consolidated into a ‘global’ script, particularly when related to other globalized discourses on the common good and human dignity. While there is strictly speaking no formal ‘global’ script as such, these commonalities are embedded in the policy documents of the various bodies or institutions considered here. Documents embody social phenomena through various modes of objectification. We have seen

an aspect of this in the objectification of chimeras and hybrids in the HA Consultation Paper and in the HA Report. These documents thereby create 'focal points' by which a particular social phenomenon is (or could be) linked or related to a broader system of reference. Referencing is a means by which organization is achieved, so that chimeras and hybrids acquire epistemological form that enables comprehension.[294] This is analogous to the way in which the facts of a particular case are (re)organized so that they are focused around a legal reference point such as 'unconscionability' in order for *meaningful* legal recourse to be sought in the law of restitution.[295] In the same way a judgment uses documents as mediation technology to confer meanings on social phenomena. It is through this drawing of relations that a subject gains conceptual coherence as object. This Chapter considers the ways in which the 'focal points' developed in a variety of 'local' scripts have been important in the shaping of 'focal points' in the HA Report.

The careful study of foreign policy documents by the BAC illustrates the transnational character of policy work. It is perhaps not often appreciate that there is a certain communicative rationality among policy-makers. After all, the study of policy documents entails an inquiry into some aspect of the institutional authors. However, one should be wary of jumping to the conclusion that policy-makers and policy bodies are intimately connected *inter se* (as perhaps a notion of legal or regulatory transplantation may suggest). The institutions in my study neither acted in

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294 I borrow this reference from Thomas Schelling, who used this term to refer to points of reference that coordinate expectations in the absence of prior agreement. Thomas Schelling, *The Strategy of Conflict*. Cambridge: Harvard University Press, 1960, at 54-58. In addition, the term 'focal points' are akin to 'fixed points' in legal reasoning, where statutes, judicial decisions and *travaux prépatoires* serve as boundaries to constrain deliberation and enable the production of an outcome or closure. See Aleksander Peczenik, Justice in legal doctrine. In Guenther Doeker-Mach and Klaus A. Ziegert (eds), *Law, Legal Culture and Politics in the Twenty First Century*. Stuttgart: Franz Steiner Verlag, 2004, pp 197-211.

295 In the US, see the decision of Justice Wright in *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445 (D.C. Cir. 1965); in the UK, the decision of Lord Denning in *Lloyds Bank Ltd v Bundy* [1975] QB 326.

concert nor in isolation. They operate under very specific sociopolitical conditions and the documents that they produce were intended to address the cognitive and broader needs of their particular circumstance. Instead these institutions appear to be associated in loose networks. Their association is neither purely a methodological construct as Marcus indicates[296] nor as structured as the 'global forms' of Stephen Collier and Aihwa Ong.[297] While these documents have been produced for specific audiences, they are, like legal rules, open textured. Arguably, these networks are embodiments of intersubjective space that these institutional authors unconsciously created. Hence this Chapter also discusses documents as an institutional technology of mediation and social relations, although the latter is admittedly more ambiguous in intent and application. We begin by considering key institutions and their scripts.

3.2 The National Academy of Sciences

In 1999, the US NBAC, appointed by President William J. Clinton, published a report on hESC research.[298] A recommendation of the NBAC was for the DHHS to establish a National Stem Cell Oversight and Review Panel. A set of guidelines was developed by the Human Pluripotent Stem Cell Review Group of the National Institutes of Health in 2000, [299] which reflected many of the recommendations of the NBAC. Both the report of the NBAC and the NIH guidelines

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296 George E. Marcus. *Ethnography Through Thick and Thin*. Princeton NJ: Princeton University Press, 1998, at 195.

297 Stephen J. Collier and Aihwa Ong, Global Assemblages and Anthropological Problems. In Aihwa Ong and Stephen J. Collier, *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems.* Singapore: Blackwell Publishing, 2005, pp 3-21 at 11.

298 National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research*. Rockville, MD: U.S. Government Printing Office, 1999.

299 National Institutes of Health, *Guidelines for Research Using Human Pluripotent Stem Cells*. *Federal Register* 65 (166, 25 August 2000): 51975.

were closely studied by the BAC when crafting the SC Report. However, by the time the SC Report was published in 2002, US federal policy on hESC research changed drastically. The guidelines of 2000 was superseded in 2001 following an executive order issued by President George W. Bush to limit the scope of federally funded hESC research to cell lines derived prior to 9 August 2001.[300] But in the absence of federal law, hESC research can be carried out in the US with private funding provided that it was not otherwise prohibited by state law.

Illustration 4. Entrance to the National Academy of Sciences in Washington D.C.

[300] The NIH then developed a set of criteria based on the limitations imposed by President Bush. National Institutes of Health, *Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry*. 7 November 2001.

In 2005, a comprehensive ethical framework was proposed by the US NAS for hESC research that was not federally funded.[301] With the foreclosure of access to public funds, the research community was unable to look to governmental bodies, particularly the NIH, for ethical or regulatory guidance. It turned to Dr. Bruce Alberts, a biochemist and at that time the President of the NAS, and the Editor-in-Chief of the illustrious journal *Science*. Recognizing the desire of the stem cell research community to avoid being perceived as mavericks, the NAS met the cost of developing its 2005 guidelines out of its own funds.[302] One cannot help but be imbued with a sense of a greater presence of being upon entering the marble lobby of the NAS building. From Galileo's star map of 1610 to Thomas Edison's incandescent light bulb patented in 1884, these images etched onto the left wall of the lobby suggest a continuum in human inventions. The NAS is a prestigious society of distinguished scholars engaged in scientific and engineering research. It was signed into being on 3 March 1863 by President Abraham Lincoln with a mandate in its Act of Incorporation to "investigate, examine, experiment, and report upon any subject of science or art" whenever called upon to do so by any department of the government.[303] The NAS expanded to include the National Research Council in 1916, the NAE in 1964 and the IOM in 1970. As such, the NAS and its constituents are sometimes referred to as the National Academies. The NAS is governed by a council of 12 members and is reported to have

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301 National Academy of Sciences: National Research Council and Institute of Medicine. *Guidelines for Human Embryonic Stem Cell Research*. Washington, DC: National Academies Press, 2005. This version of the NAS Guidelines is accompanied by a detailed explanatory text that is not reproduced together with subsequent revisions.

302 Interview with Dr. Fran Sharples, Director, Board on Life Sciences, National Academy of Sciences, 21 July 2011. Dr. Sharples explained that the Board of Life Sciences is part of the National Research Council, which is a private non-governmental body. However, its work has essentially been funded by way of federal contracts. This showed that human embryonic stem cell research was considered to be a very important area for the NAS to fund the development of guidelines. Subsequent amendments to the 2005 guidelines continued to be funded mainly by the NAS, although some funding was also obtained from charities, such as the Howard Hughes Institute.

303 Rexmond C. Cochrane. *The National Academy of Sciences: The First Hundred Years 1863-1963*. Washington D.C.: National Academy of Sciences, 1978, at 596. Cochrane indicates the NAS's most famous and long-lived ancestor as England's Royal Society, which received its charter from Charles II in 1662.

approximately 2,100 members and 380 foreign associates, of whom nearly 200 have won Nobel Prizes.[304]

The first version of the *Guidelines for Human Embryonic Stem Cell Research* issued in 2005 was prepared by an expert committee co-chaired by biochemist Richard Hynes and bioethicist Jonathon Moreno, and supported by a secretariat that was headed by Dr Fran Sharples. These guidelines were subsequently amended on three occasions; in 2007[305], in 2008 to include iPSC technology,[306] and again in 2010 to reflect changes made by the NIH under the Obama Administration.[307] Taken together, the NAS Guidelines (the 2005 Guidelines, as amended in 2007, 2008 and 2010: the "NAS Guidelines") recommend the establishment of an ESCRO committee for the review of any research involving hES cells or human iPS cells. This is regardless of the source from which such cells are derived (ie whether from a human embryo or from SCNT).[308] While it may share some members with an IRB, an ESCRO committee is not a subcommittee of, or a substitute for, the IRB. Its purpose is to provide an additional level of review and scrutiny due to complex issues raised by hES cell research.[309] As for the standard of review, the NAS Guidelines present three categories: (a) research that does not require additional

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304 The data is drawn from the website of the NAS: www.nasonline.org.

305 National Academy of Sciences: National Research Council and Institute of Medicine, *2007 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research*. Washington, DC: National Academies Press, 2007.

306 National Academy of Sciences: National Research Council and Institute of Medicine, *2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research*. Washington, DC: National Academies Press, 2008.

307 National Academy of Sciences: National Research Council and Institute of Medicine, *Final Report of the Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research*. Washington, DC: National Academies Press, 2010. Amendments were mainly introduced to reflect President Barack Obama's Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, which was issued on March 9, 2009.* The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

308 *Ibid*, Guideline 1.1(a).

309 *Ibid*. See Guideline 2.

review by the ESCRO committee, (b) research that requires additional review and approval by the ESCRO committee, and (c) research that should not be conducted at this time.[310] Most research involving human-animal chimera or cytoplasmic hybrids falls into the second category. As such, the research will have to be reviewed by the IRB, IACUC, Institutional Biosafety Committee and the ESCRO committee.[311]

The NAS Guidelines limit experimentation on a human embryo or embryo-like constructs (such as cytoplasmic hybrids) to 14 days of development. It further recommends the prohibition of the implantation of such hybrids into a uterus.[312] Even with the breakthrough of iPSC technology, cytoplasmic hybrids (and SCNT more generally) is still valued as a research tool to facilitate understanding of the reprogramming process of somatic nuclei. In incorporating a new set of guidelines that relate specifically to iPSC technology,[313] the orientation of the NAS reflects that of the NBAC in treating the subject of pluripotency in a more generic manner. As for animal chimeras, the NAS considers experiments incorporating hES cells into postnatal animals to be an essential form of preclinical testing, similar to standard testing of drugs, transplants, and medical devices in animals before human clinical trials.[314] Concerns over such experiments mainly pertain to the possibility of the hES cells or neural derivatives conferring 'higher-order' brain functions in the animal, or of human cells arising in non-human germline.[315] It observes that the issue regarding the potential for contribution to brain function is not easily resolved and should be explored through animal experiments. In addition, due care is required in conducting

310 *Ibid*. Guideline 1.3.
311 *Ibid*, Guideline 1.3(b)(i) and (ii).
312 *Ibid*, Guideline 4.5.
313 *Ibid*, Guideline 7 (Recommendations for research use of non-embryo-derived human pluripotent stem cells).
314 National Academy of Sciences: National Research Council and Institute of Medicine, *Guidelines for Human Embryonic Stem Cell Research*. Washington, DC: National Academies Press, 2005, at 39.
315 *Ibid*, at 40.

experiments that create such possibilities.[316] Concerns have also been expressed over germline modifications, but these could be more easily addressed by disallowing the chimeric animals to breed. In summary, the degree of ethical concern over incorporation of hES cells into an animal will vary with its stage of development.[317]

The proposed prohibitions in the third category (ie experiments involving the incorporation of hES cells into other species at the embryonic stage) similarly apply to non-embryo-derived human pluripotent stem cells. The NAS maintains the position that the following types of research should not be permitted at this point of time:[318] (a) experiments that involve transplantation of human pluripotent stem cells into human embryos; and (b) research in which human pluripotent stem cells are introduced into nonhuman primate embryos, pending further research that would clarify the potential of such introduced cells to contribute to neural tissue or to the germline. In addition, the NAS continues to express caution over the use of human neural stem cells[319] and potential germline modification.[320]

On 9 March 2009, President Barrack Obama removed restrictions on hES cell research imposed by President Bush.[321] Following this, a new set of guidelines was issued by the NIH.[322] In the creation of human-animal chimeras, these guidelines reflect the position of the NAS in that

316 *Ibid*.

317 National Academy of Sciences: National Research Council and Institute of Medicine. *Guidelines for Human Embryonic Stem Cell Research*. Washington, DC: National Academies Press, 2008, Guideline 6.

318 *Ibid*, Guideline 7.3(c)(iii).

319 *Ibid*, Guideline 7.4.

320 *Ibid*, Guideline 7.5.

321 Barack Obama (2009). *Removing Barriers to Responsible Scientific Research*. Executive Order 13505. For a discussion of some developments following this reversal of policy, see Mary A. Majumder and Cynthia B. Cohen, Future Directions for Oversight of Stem Cell Research in the United States: An Update. In *Kennedy Institute of Ethics Journal* (2009) Vol. 19 No. 2, pp. 195-200.

322 National Institutes of Health, *Guidelines for Research Using Human Stem Cells*. *Federal Register* 74, 128 (7 July 2009): 32170-32175.

research involving the following will not be eligible for funding:[323] (a) the introduction of hES cells or human iPS cells into nonhuman primate blastocysts; and (b) the breeding of animals where the introduction of hES cells or iPS cells may contribute to the germline. But unlike the NAS Guidelines, the NIH denies funding for research "using hESCs derived from…somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes".[324] Consequently, a research involving the derivation of stem cell from a cytoplasmic hybrid embryo will not be eligible for NIH funding. This position is more conservative than that proposed by the NBAC of the Clinton Administration.

Although the NAS is not a conventional standards-setting government body like the NIH, the circumstance under which the first version of the guidelines on stem cell research was produced rendered the NAS a surrogate of the NIH and the *de facto* standards body in the US.[325] The relationship between the NAS and the NIH is often not as straightforward as it may seem. Dr Sharples explained that NIH could be regarded as a client of the NAS in that it has received substantial funding of about US$10 million in grants. However, there has always been some tension between funding that the NIH provided to the NAS and funding that it could otherwise provide directly to investigators. In the current climate of tight budget constraints, the NIH was expected to scrutinize the projects that the NAS conducts. To quote Dr Sharples: "NIH has less money, we get less money".[326] She further observed that with Dr Francis Collins as Director of the NIH, there might be a preference for it to can get advice directly from the scientific

323 *Ibid*, at 32175, Guideline IV.
324 *Ibid*, Guideline V.
325 Cohen and Majumder argue for a more uniform, authoritative and participatory approach, with NIH taking the lead. Cynthia B. Cohen and Mary A. Majumder, Future Directions for Oversight of Stem Cell Research in the United States. In *Kennedy Institute of Ethics Journal* (2009) 19, 1: 79-103, at 89-90.
326 Interview with Dr. Fran Sharples, Director, Board on Life Sciences, National Academy of Sciences, 21 July 2011.

community rather than to go through the NAS. However, she also indicated that it could be appropriate to exclude the government in discussions on certain issues in order to have a "safe forum" or not have the authorities "breathe down your neck". This was a reason for not consulting the government when the NAS guidelines were revised from 2007. As a practical matter, it appears clear that the NAS guidelines have been taken to be the *de facto* governance standards for the US, and the key features of the ethical framework proposed by the NAS are largely reflected in the ethical rules of the ISSCR and the CIRM, a statutory body established by the State of California to fund stem cell research. We consider each of them in turn.

3.3 International Society for Stem Cell Research

The ISSCR was formed in 2002 as an international professional organization of stem cell scientists. It meets annually, mainly in North America, and has co-organized regional meetings. In June 2012, it will hold its tenth meeting in Yokohama, Japan. The ISSCR has been presided by well-established stem cell researchers like Irving Weissman, who served as the immediate past President.[327] In 2007, it launched the journal *Cell Stem Cell* as a high-end forum for stem cell biology. A year later, experts in law and public policy were involved in its 'Global Forum' series, and a Global Advisory Council was formed to help the ISSCR set a strategy for advancing stem cell research and public education.[328] It was observed that since its founding, the ISSCR "remains the only international membership society that embraces researchers, clinicians, ethicists and policymakers, industry representatives, civic leaders, and patient advocates. This

[327] George Q. Daley, Letter from the President, *Cell Stem Cell* (2008) 3: 151-152.

[328] George Q. Daley, Heather M. Rooke and Nancy Witty, Global Forum Discusses Stem Cell Research Strategy, *Cell Stem Cell* (2007) 2: 435-6.

broad constituency both motivates and enables the ISSCR to present a united voice for the continued global support of stem cell research and the exchange of scientific information".[329] Stem cell researchers in Singapore have been involved in the scientific meetings of the ISSCR. On a number of occasions, members of the BAC have also been involved in the meetings as a component of which would relate to ethics. It has been in part through engagement that the views of the ISSCR are important in the deliberations of the BAC. For the BAC Secretariat, being acquainted with a number of the scientists and policy-makers involved in the ISSCR added familiarity and perspective. Recognition by the ISSCR itself of the need to constantly recreate itself to enhance relevance and distinction contributes to their credibility among policymakers.[330]

Three documents provide guidance for the conduct of all human embryonic stem cell research, including research involving cytoplasmic hybrids and chimeras. The first set of guidelines published in December 2006 set out the general regulatory framework for hESC research.[331] They exclude research on animal stem cells, human stem cells that are not known to possess totipotent or pluripotent potential, or the transfer of animal cells into humans at any stage of development. As such, the focus of the ISSCR was on experimental rather than therapeutic application of human pluripotent cells. Similar to the ESCRO committee, the ISSCR proposes a separate review mechanism for stem cell research, but in the form of a process referred to as Stem Cell Research Oversight (or SCRO).[332] The three categories of stem cell research for

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329 Nancy Witty, Strategic Planning: Progress and Potential, *Cell Stem Cell* (2007) 1: 383-6, at 383.

330 Take for instance the ISSCR's letter to the German government expression support for revisions to the 2002 Stem Cell Act. International Society for Stem Cell Research, Press Release: *Letter to German Government supporting changes to Stem Cell Act, 2002*, 7 March 2008. It also provided feedback to the NIH on its 2009 guidelines for stem cell research: International Society for Stem Cell Research, Press Release: *ISSCR Comments on Draft Guidelines for Embryonic Stem Cell Funding*, 22 May 2009.

331 International Society for Embryonic Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, 2006. Available at: www.isscr.org.

332 *Ibid*, at 5, paragraph 8 (Recommendations for Oversight).

experiments that are permissible after standard review, permissible after additional and comprehensive review by and impermissible reflect the ethical framework of the NAS.[333] However, the ISSCR Guidelines differs from the NAS Guidelines in that the incorporation of hES cells into nonhuman primate embryos or of any embryonic stem cell into human embryos is not prohibited. It does specify caveats relating to the proportion of human stem cells transferred, the likely integration into critical tissues such as the germline and central nervous system, and the transfer of human cells into non-human primates.

A year later, the Ethics and Public Policy Committee of the ISSCR published a report that specifically addressed the subject of animal chimeras. It emphasized the importance of animal chimeras as research tools and to avoid "unwanted stem cell exceptionalism".[334] Operationally, monitoring and data collection should be based upon a sound assessment of the developmental trajectories that are likely to be affected, and the epigenetic context of regulation in which the mixed genes or cells are going to be deployed should be taken into account. Data collection should be related to known functional links, and evaluated in a scientifically legitimate manner. The ISSCR observes that no single test, such as the percentage presence of human derived cells in the brain, should be necessarily required, unless its functional link to pertinent physical or mental qualities is either demonstrated or is consistent with scientific knowledge or scientifically reasonable inferences concerning whether, in the context of other data, it will be a valid predictor of sentience.[335] Chimera neuroscientific research involving human stem cells or their direct derivatives, in hypothetically approximating some aspects of human functioning, may thus

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333 *Ibid* at 6-7, paragraph 10 (Categories of research).

334 International Society for Stem Cell Research, Ethical Standards for Human-to-Animal Chimera Experiments in Stem Cell Research, *Cell Stem Cell* (2007) 1: 159-163, at 161.

335 *Ibid*.

demand accepted or new specialized cognitive and other assessments of the sort conducted in neuroscientific research.

More recently, a report was published to consider if the creation of cytoplasmic hybrids is scientifically justified. This scientific and (to a lesser degree) ethical evaluation was undertaken in the light of some recent developments, notably those in the UK.[336] Contextualizing SCNT (referred to as 'iSCNT', where the technique of SCNT is applied to the creation of cytoplasmic hybrids, in contrast to the more conventional hSCNT in therapeutic cloning) alongside iPSC technique in the broader technology of nuclear reprogramming research, the ISSCR recognizes that the latter is a much simpler way of deriving cells with pluripotent qualities. However, there are important differences between the two techniques. First, the questions that these techniques seek to answer in basic biology are different. The epigenetic reprogramming entailed in iPSC is essentially gene-based whereas SCNT is concerned with oocyte-driven reprogramming on human somatic cell nuclei. Second, SCNT provides important information on human embryogenesis, from which physiological mechanisms and pathological aberrations can be better understood. It is as yet unclear if a viable embryo can be produced from gametes or embryonic stem cells derived from iPSC. If such an embryo can be produced from iPSC, there will only be a clearer basis at that time for re-evaluating the relevance of SCNT. Third, not enough is known about iPSC to "confidently abandon all other research pathways aimed at obtaining pluripotent cells."[337] As we have seen, this is a position that is consistent with the BAC's in its HA Consultation Paper. The ISSCR concludes that rather than rendering SCNT obsolete or redundant, the iPSC technique is complementary. It further agrees with the proposal of the AMS

[336] International Society for Stem Cell Research, Ethics Report on Interspecies Somatic Cell Nuclear Transfer Research, *Cell Stem Cell* (2009) 5: 27-30, at 27.

[337] *Ibid*, at 28.

that comparison between pluripotent cell lines derived by hSCNT versus iSCNT should be allowed.[338]

As for the ethical aspects of the research, the ISSCR did not view these to be significantly different from those attending to animal chimeras, even if the latter involved a mixture of genetically different cells rather than a mixture of genetic material within a cell. It did recognize that continued emphasis on the importance of SCNT may result in the exploitation of women for eggs. However, the research should not be precluded only on the basis of this risk if the development of stem cell-based therapies is of social or humanitarian importance. The 'common good' basis similarly is evident.[339]

3.4 California Institute for Regenerative Medicine

In November 2004, the California Stem Cell Research and Cures Act (Proposition 71) was passed by a state-wide ballot. The Act created the CIRM, endowed it with a research fund of $3 billion (to be expended over a decade) and constituted a Standards Working Group ("SWG") to recommend scientific, medical and ethical regulations. In July 2005, the SWG recommended that the 2005 NAS Guidelines be adopted as interim regulations. These regulations became the subject of a year-long public consultation from July 2005 to July 2006, and were finalized in

338 *Ibid*.
339 *Ibid*, at 29.

November 2006 after the revisions were reviewed and approved by the California Office of Administrative Law.[340]

The connection between the BAC and the CIRM was Professor Bernard Lo, who was the co-Chair of the SWG of the CIRM and an expert advisor to the BAC. He is also a Council member of Institute of Medicine, under the auspices of which the NAS Guidelines have been published. When we met in August 2008, Professor Lo said that the guiding principle of the CIRM is to encourage institutions to develop best practices to oversee new and rapidly developing field and ensure flexibility in the SCRO structure and function.[341] He added that a regulatory regime should be rigorous, but flexible, in order to be effective in providing some assurance to those who are opposed to some (but not all) forms of stem cell research. He identified the regulatory challenges of the CIRM to include specificity and appropriate implementation of guidelines.[342]

On the subject of human-animal mixing, Professor Lo said that bioethics in the US tends to start with an emotive response. The reliance of the President's Council on an intuitive feeling of repugnance in developing moral arguments is illustrative.[343] Such research is also seen to violate religious doctrine and undermine human dignity. He disagreed with the approach of the President's Council, and indicated the need to distinguish between religious beliefs that guide personal behavior from values that guide public policy. The reasons underlying public policies must be understandable and persuasive. An instance when human dignity is seen to be violated is

340 Geoffrey P. Lomax, Zach W. Hall and Bernard Lo. Responsible Oversight of Human Stem Cell Research: The California Institute of Regenerative Medicine's Medical and Ethical Standards, *PLoS Medicine* (2007) 4(5): 0803-0805.

341 CIRM Medical and Ethical Standards Regulations, Title 17, California Code of Regulations, §100040, 25 August 2011 (Reformatted and Approved).

342 Interview with Professor Bernard Lo, 16 August 2008.

343 See William Saletan, The Thing Is: At the bioethics council, human nature denies human nature. *Slate*, 7 March 2005.

if an animal develops characteristics considered to be specifically human, such as neurological functions or production of human germ cells. There may also be such a concern when large portions of human genetic materials are transferred into an animal. The importance of distinguishing among the different types of human-animal mixing, some of which has been extensively conducted already, includes: (a) introducing human genes into nonhuman animals, as in the case of transgenic animals, and (b) injecting human stem cells into nonhuman animals, which is undertaken to demonstrate pluripotentiality through the formation of teratomas in immunodeficient mice. Testing on animal models is also carried out before clinical trials in humans for proof of principle or as preclinical studies to establish safety and dosage.

As the NAS Guidelines have been substantially adopted by the CIRM, the introduction of hESC into animals at any stage of development will require SCRO review.[344] In particular, there must be acceptable scientific rationale and the probable differentiation and integration of human cells into animal tissue must be evaluated. In addition, the following research is currently not eligible for CIRM funding:[345]

(a) Breeding of nonhuman animal into which hESCs have been introduced;

(b) Introducing hESCs into nonhuman primate blastocysts; and

(c) Introducing hESCs into human blastocysts, as this could lead to confusion as to which DNA is controlling.

344 CIRM Medical and Ethical Standards Regulations, Title 17, California Code of Regulations, §100070(e), 25 August 2011.

345 *Ibid*, §100030.

The CIRM has extended this prohibition to all pluripotent stem cells as Professor Bernard Lo indicated that regulations must change to keep pace with scientific developments. In addition, he was of the view that attention would most likely shift to iPSC technology since pluripotent stem cell lines could be derived through it. The CIRM further requires that donors of materials for CIRM-funded research be informed that derived cells may be transplanted into animals.[346] This is to give effect to another core ethical principle of the CIRM, which is the requirement for informed consent from donors of biological materials to be obtained (with some exceptions).[347] The core principles or objectives of the CIRM were also mentioned when I met with Dr. Geoffrey Lomax at his San Francisco office in May 2009. Dr. Lomax was the senior officer who supports the work of the SWG, and was also the co-chair of the Interstate Alliance on Stem Cell Research. In a paper that he co-authored, the overall objectives of the CIRM regulations are set out as (a) encourage research institutions and researchers to develop best practices for ethical conduct of human stem cell research, (b) avoid unnecessary regulatory burdens, (c) facilitate collaboration to accelerate scientific progress, (d) be consistent with existing laws, regulations and ethical guidelines, and (e) involve the public in developing regulations.[348] Much of our discussion at the meeting and then over lunch was focused on public involvement.[349] Understandably, public support has been critical to the CIRM by virtue of its very existence. This may account for the sense of openness that the CIRM office exudes, undoubtedly enhanced by the colorful electromicroscopic portraits of stem cells that seem to reach out to you in their

346 *Ibid*, §100100(b)(1)(E).

347 The other two core ethical principles are: Review by independent committee (SCRO Committees in particular); and no payment beyond expenses to research oocyte donors (although payment may be made for oocytes donated for fertility treatment).

348 Geoffrey P. Lomax, Zach W. Hall and Bernard Lo. Responsible Oversight of Human Stem Cell Research: The California Institute of Regenerative Medicine's Medical and Ethical Standards. In *PLoS Medicine* (2007) 4(5): 0803-0805.

349 Interview with Dr. Geoffrey Lomax, Senior Officer, Standards Working Group, CIRM, 12 May 2009.

own language. Quite aptly, a sign placed next to the main reception desk reads: “Stem Cell Place”.

Illustration 5. Main reception of the California Institute of Regenerative Medicine

When I asked about the NAS Guidelines, he said that while it served as a model for the CIRM regulations, federal laws and guidelines – particularly the Common Rule and the NIH Guidelines – were also influential. Even then, the regulations must be tailored to suit local requirements. He views the harmonization of standards on a nationwide (and even at an international) level to be important, although individual states will still be key drivers of stem cell policies in view of the difficulties in forging broad consensus on the subject and in engaging with the public on a very

broad scale. Prior to heading out for lunch, I was given a draft manuscript that he wrote.[350] The locally-tailored character of the California regulation reminded me of Professor Lo's comment that Proposition 71 is more specific in contrast to the UK HFE Amendment Bill. The latter does in fact encompass many broad social issues relating to reproduction and familial relations. Furthermore, public misapprehension of research involving human-animal mixing would likely be high in the US, and hence not politically expedient to craft broad legislation. An informant familiar with the situation in the UK said that the British government attempted to get through as many political objectives as possible, because the HFE Act of 1990 turned out to be too restrictive for research. While he did have some reservation about the breadth of the legislation, he noted that the British Parliament has been relatively liberal on the subject. Allowing the creation of a human embryo for research is a good example of its unique position in Europe.[351]

3.5 Academy of Medical Sciences

In the previous chapter, we have considered the circumstances under which the subject of human-animal combinations, especially cytoplasmic hybrids, became problematized in UK public policy. With the prospect that stem cell research could be curtailed when the time came for policy review of the regulatory framework established by the HFE Act, the AMS's report on interspecies embryos became the focal point in offering a counter trajectory. As we have also seen, the report has been important in a number of ways, including the provision of a vocabulary

350 Geoffrey Lomax. Rejuvenated Federalism: State-Based Stem Cell Research Policy. In Benjamin J Capps and Alastair V Campbell (eds), *Contested Cells: Global Perspectives on the Stem Cell Debate*. London: Imperial College Press, 2010, pp 359-375.

351 Fieldnotes, 15 August 2008.

to better enable discussion on human stem cell research and inter-species embryos, and the specification of the four main types of human-animal combinations as hybrid, chimera, transgenic animal and cytoplasmic hybrid.[352] Here, we consider the key principles and governance framework proposed by the AMS for transgenic and chimeric animals that contain significant amounts of human genetic material.

Where human gametes and embryos are concerned, the AMS attempted to work within the regime established by the HFE Act. However, the more important discussion in the report related to the broader governance structure that extended beyond the established statutory regime to cover human-animal combinations in stem cell research more generally. It is in this respect that the ISSCR has been a dominant influence, especially in structuring governance as a categorical review process.[353] In particular, three categories of review were proposed. Like the ISSCR, the AMS does not disapprove of the introduction of human pluripotent stem cells into a non-human primate or human embryo if there is sufficient justification for the research. It similarly sets out caveats relating to the proportion of human stem cells transferred, the likely integration into critical tissues such as the germ-line and central nervous system, and the transfer of human cells into non-human primates. If transgenic and chimeric animals contain significant amounts of human genetic material, an appropriate conceptual and regulatory framework will have to be considered.

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352 Academy of Medical Sciences. *Inter-species embryos*, London: Academy of Medical Sciences, June 2007, at 22. A table sets out the definitions of hybrids, chimeras, transgenic and cytoplasmic hybrids at three different stages of development: as cells and cell-lines, as embryo and as animals.

353 *Ibid*, at 35.

When I met with Dr. Helen Munn in April 2008, the HFE Amendment Bill has successfully passed through the House of Lords and was being debated in the House of Commons. The HFE Amendment Bill was introduced in the House of Lords on 8 November 2007. The intent was to update (but otherwise retaining) the "current model of regulation and the basic foundations of the existing law contained in the Human Fertilisation and Embryology Act 1990" in order to "help maintain the UK's position as a world leader in reproductive technologies and research".[354] Of interest to the BAC is one of the main elements of the Bill, which is to increase the scope of legitimate embryo research activities, including 'interspecies embryo'. The Bill initially followed the terminology of the AMS report in its reference to 'interspecies embryos', but this was replaced by 'human admixed embryos'. Dr. Munn, a young Oxford-trained scientist, was the Director of Medical Science Policy at the AMS, and also served as Secretariat to the report's Working Group. She said that this change was introduced by Lord MacKay so as to indicate that a cytoplasmic hybrid embryo is effectively 'human'. This classification is important because the HFEA does not regulate non-human embryo research. And as noted in the AMS report, *in vitro* animal embryo research did not appear to fall within any regulatory purview. Apart from this, (then) British Prime Minister Gordon Brown has lifted the 'Party Whip' to allow free vote on the issue after strong protest was received as some members of his party felt that they could not act against their conscience.[355] Dr. Munn shared that those in the government who opposed the use of 'human admixed embryos' are also those who said 'no' to hESC research. On the whole, there was strong support for the HFE Amendment Bill as it is seen as the "flagship of knowledge economy in the UK".[356]

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354 Elizabeth Shepherd, *Human Fertilisation and Embryology Bill [HL]*, HL Bill 6, 2007-08. London: House of Lords Library Notes, 2007, at 1.

355 Polly Tonybee, Religion doesn't rule in this clash of moral universes, *The Guardian*, 25 March 2008.

356 Fieldnotes, 1 April 2008.

Earlier on, Professor Martin Bobrow told me that he personally did not expect the Bill's provisions for interspecific hybrids to be especially controversial in the UK, although there was a vocal minority in strong opposition.[357] Many of the legislative amendments proposed in the Bill related to sociological issues such as marital status and the welfare and rights of children. The provisions that related to human-animal combinations were included to ensure that these constructs would fall within the regulatory purview of the HFEA. He indicated that the term 'interspecies embryos' had been revised to 'human admixed embryos', which referred to human embryos with some non-human genetic material, as opposed to animal embryos with human material. The Bill was specifically concerned with human embryos and so would not include transgenic animals. As for animal chimeras, Professor Bobrow said that they would require more thought, especially in relation to the introduction of human cells (such as neural cells) into an animal (such as a monkey). In addition, it would be important not to confuse research involving human-animal combinations at an embryonic level with research using animal chimeras. The UK will have to deliberate on the latter in the near future, as there have been reports of significant amount of human neural cells being introduced into non-human primates. Such research is contentious in the eyes of the public and there are possibly no legal or practical control mechanisms apart from IRB review. Reflecting the concerns of researchers in general, Professor Bobrow similarly indicated that care should be taken not to interfere with certain well-established use of human-animal combinations such as transgenic animals. Careful working through is required to determine where the problems lie, what the regulations are, who should be the controller and related issues.

[357] Fieldnotes, 19 January 2008.

Illustration 6. Carlton House Terrace as home to the Academy of Medical Sciences

The AMS was formed in 1998 to develop and support UK medical science and individual biomedical researchers into the future. As an independent academy of experts, it acts as a champion for exploration of knowledge, a guardian of intellectual rigor and excellence, and an advisor on national public policy issues. It is housed in the impressive No. 10 Carlton Terrace of the British Academy, whose interior has largely survived the Second World War. The three-flight black marble staircase was modeled in French classical tradition, and the largest of the grand corniced ceilings in the Lecture Hall has an unfinished *trompe l'oeil* in the style of late

Delacroix.[358] The area itself is home to many other learned societies and academic organizations including the Institute of Materials, Minerals and Mining, the Royal College of Pathologists, the Royal Academy of Engineers, and the Royal Society. Dr. Munn said that the report was put together relatively quickly in view of the political developments on the subject. At that time, there was "not much around" by way of relevant materials from the EU. But as is evident from the report, the guidelines of the NAS and the ISSCR, as well as the regulations of the CIRM, were relied on by the AMS. Consultations were conducted with regulatory authorities like the HFEA and some assistance was sought from collaborative partners like the Wellcome Trust and the Science Media Centre. Reflecting back, Professor Bobrow said that the report has been important in directing scientific interests in a way that could help steer policy development.[359] Its substantive effect was perhaps most evident at the meeting with Parliamentarians, where science and scientific interests appeared to speak with one voice.

3.6 Danish Council of Ethics

Shortly after the publication of the AMS report, the Danish Council of Ethics (DCE) and the Danish Ethical Council for Animals produced a report on research involving human-animal combinations entitled *Man or Mouse*.[360] The BAC did not have any direct connection with its Danish counterpart, but the report provided some (needless to say timely) insight into European

358 British Academy, *Carlton House Terrace*. London: British Academy, 2007, at 4.
359 Interview with Professor Martin Bobrow, 2 August 2010.
360 Danish Council of Ethics (with the Danish Ethical Council for Animals). *Man or Mouse: Ethical aspects of chimera research*. Copenhagen: Danish Council of Ethics, 2007.

thinking on the subject.[361] The two main issues considered in the report are, whether human-animal hybrid and chimera research should be prohibited altogether, and what considerations policy-makers should take note of if such research is not prohibited.

A majority of both councils did not consider ethical and moral concerns to be so convincing that hybrid and chimera research should be prohibited. Six ethical arguments, based on dignity of humans and animals, were identified as reasons for intuitive revulsion against human-animal admixtures, and each of these arguments were found to be inadequate.[362] Instead, an approach based on concrete assessment carried out on a case-by-case basis was preferred. In order to facilitate this approach, the councils were of the view that the current regulatory framework would have to be reviewed by policy-makers. In particular, the councils indicated that the current research legislation should be amended to empower the relevant authority to regulate (and/or prohibit) experiments that relate to cognitive functions and reproduction.[363]

In the scientific review conducted up to 2006, various types of research involving a variety of human to animal and animal to animal combinations are discussed.[364] A number of examples involving the transplantation of animal cells (eg neurons from pig fetuses), tissues or organs from animals into humans are also described. It reports that there is no published example of true hybrids between humans and animals, transplantation of cell nuclei from animals to enucleated human ova, chimeras of human embryos or fetuses with non-human cells, insertion of human

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361 Arguably, the approach is Scandinavian rather than continental European. However, the reasoning applied is European in the sense that it has been undertaken within a conceptual framework demarcated by European documents such as the *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine*. *Ibid*, at 27-8.

362 Danish Council of Ethics (with the Danish Ethical Council for Animals). *Man or Mouse: Ethical aspects of chimera research*. Copenhagen: Danish Council of Ethics, 2007, at 97-99.

363 *Ibid*, at 99-100.

364 *Ibid*, at 68-86 (Appendix).

embryonic stem cells into blastocysts from animals and human embryos inserted into an animal womb. Similar to the approach of the BAC, current scientific work was used to frame the scope of ethical and legal discussions.

In a view similar to that of the AMS, the creation and use of transgenic animals have been earmarked for consideration in a separate report as such research is "a very extensive and wide-ranging sphere".[365] The Councils also indicate the need to harmonize a number of different laws that would apply separately to the human or animal portion of an experiment. The DCE observes that Danish law currently draws a sharp division between 'human' and 'animals'. The difficulty posed by research involving chimeras and hybrids is that they are either unregulated or will have to be forced within one of these categories, which could result in much ambiguity. Professor Agger said that as a practical matter, it was unclear if cytoplasmic hybrids would fall within the regulatory purview of the Ministry of Justice (which regulated research involving animals) or the Ministry of Health (since human biological materials are entailed).[366] As we have seen, the UK was confronted with the same challenge. Also related to the difficulty of legal categorization, it is unclear if the creation of a cytoplasmic hybrid embryo is regulated by law as it is equivalent to a 'human' embryo if assessed in terms of its genetic composition.[367] If so, it may be precluded by another legal provision that prohibits the creation of human-animal crossbreeds.[368] The

365 *Ibid*, at 10.

366 Interview with Professor Peder Agger, Chairperson of the Danish Council of Ethics, 31 July 2010.

367 Section 25 of the Danish Act on a Scientific-ethical Committee System and Handling of Biomedical Research Projects (1992) is the key provision that governs embryo research, but it applies only to human embryos, not animal embryos. This begs the question as to whether a cytoplasmic hybrid created through the transplantation of a human somatic nucleus into an animal egg will result in a human embryo. Danish Council of Ethics (with the Danish Ethical Council for Animals). *Man or Mouse: Ethical aspects of chimera research*. Copenhagen: Danish Council of Ethics, 2007, at 27-8.

368 *Ibid*, at 32-33. Section 28(3) of the Danish Act on a Scientific-ethical Committee System and Handling of Biomedical Research Projects (1992) prohibits: "Experiments whose purpose is to make possible the

applicability of this provision is ambiguous given that there is no scientific interest in developing a cytoplasmic hybrid embryo into a fully grown organism. A more fundamental difficulty lies in the prohibition against creating a 'human' embryo for research.[369] Still, this would depend on how a cytoplasmic hybrid embryo is to be classified. If – based on its genetic composition – the creation of a cytoplasmic hybrid embryo amounts to the creation of a human embryo even if not through the process of IVF, such research is prohibited.[370] The DCE did not consider this outcome to be satisfactory as a cytoplasmic hybrid embryo could not be understood as ethically equivalent to a human embryo created through IVF. In addition, preference is expressed for a single overall evaluative framework that could apply to both human and animal research rather than two separate and distinct systems.[371] This arrangement, if taken up, will be a major contrast from the approach in the US, Singapore and to some degree the UK where, as we have seen, distinct institutions have been developed to govern exclusively human or animal research, not both. However, the research governance structure in Denmark is different in that its research ethics committees (equivalent to IRBs in the US and in Singapore) are not institution-based. Instead, they are grouped together by regions and are hierarchical in that researchers may appeal against a decision to the Central Research Ethics Committee.[372] There are some similarities with the UK system of ethics review, possibly modeled after the National Health Service.

I visited the Secretariat of the DCE in March 2008 and met with Ms. Anne Lykkeskov. The office was housed in a traditional multi-storey terrace building with a classic elevator no taller

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production of live human individuals who are crossbreeds with a gene stock incorporating elements from other species".

369 *Ibid*, at 28-9.

370 *Ibid*, at 31.

371 *Ibid*, at 100.

372 Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects (2003).

than two meters and could admit a maximum of five persons. The office itself was impressively modern and the design *advant garde*. It so happened that on that day, Ms. Lykkeskov would also be giving a lecture to a group of visiting Austrian graduate students. We spoke for about an hour and a half before the lecture began. The lecture itself was structured in a manner similar to lectures that I have given about the BAC – history of the organization, past activities, current activities, future activities, and finally, a question and answer session. The DCE was established in 1987 as politicians did not feel adequate to regulate matters relating to the human body.[373] In 2005, its original mandate set out in legislation was expanded. Earlier on in our meeting, Ms. Lykkeskov told me that the main function of the DCE is not to direct policy but to inform politicians by setting out sensible arguments and approaches. Its link to the legislature is hence not as close as its counterparts in Sweden and Norway. In this respect, the DCE resembles the role of the BAC. Neither the Danish government nor the Singapore government is obliged to follow the recommendations proposed by its respective bioethics advisors. When I met the Chairperson of the DCE in 2010, Professor Peder Agger similarly indicated that the Council's role was to highlight the complex dilemmas in biomedical research, and it was for the Danish government to decide on the best course of action, if any was to be taken.[374]

[373] Fieldnotes, 14 March 2008.
[374] Interview with Professor Peder Agger, Chairperson of the Danish Council of Ethics, 31 July 2010.

Illustration 7. Ms. Anne Lykkeskov's Presentation to Austrian Students

As for the selection of topics for consideration, the DCE operates in a manner similar to the AMS in that it is for a council member (or academy fellow in the case of the AMS) to initiate. The topic of hybrids and chimeras is considered appropriate as there is strong public interest in the impact of science on the environment and human reproduction. Since the publication of its report, the Danish Parliament (Christiansborg) has asked for hearings and workshops to be organized. I met Ms. Lykkeskov's colleague, Ms. Lise Wied Kirkegaard several months later in Paris and was given a copy of publicity for a public forum. It drew about two to three hundred participants, many of whom were civil servants, politicians and students.[375]

[375] Interview with Ms. Lise Wied Kirkegaard, Head of the Secretariat, Danish Council of Ethics, 31 July 2010.

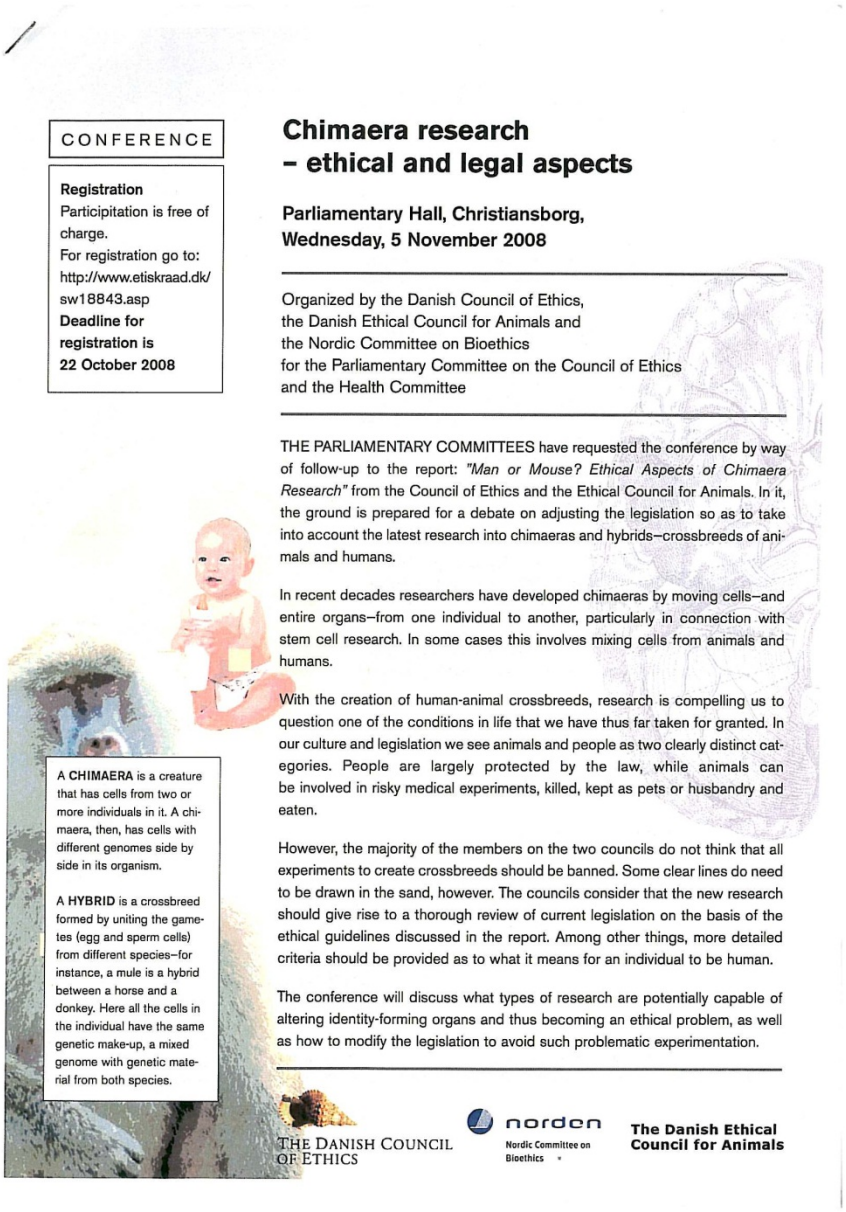

Illustration 8. Publicity for Workshop on Chimera Research in Denmark

Ms. Lykkeskov shared that, in preparing the report, the guidelines of the NAS and ISSCR were considered. However, the emphasis was in setting out arguments that were relevant to local conditions. As such, discussion on law and ethics was relatively extensive. When I asked about how the phenomenon of 'law' is perceived in Denmark, Ms. Lykkeskov said that it is decisive and directive, and not really seen as part of everyday life. Her impression is that people are

'generally satisfied' with the current operation of law although some changes may be required in the light of scientific advancement. In a separate interview,[376] Ms. Kirkegaard said that the Council of Europe's Convention on Human Rights and Biomedicine provided an important deliberative and analytical framework,[377] and there was as such much deliberation over its application to the subject of hybrids and chimeras. A lawyer by training, Ms. Kirkegaard explained that this Convention is important as it has been ratified by Denmark. However, international treaties do not automatically become part of Danish law, as international law is considered a separate system of law under dualistic principle of Danish legal tradition (arguably embodied in Article 19 of the Danish Constitution). In particular, there has been much discussion on whether the creation of cytoplasmic hybrids and chimeras could be interpreted as violating human dignity under the Convention, and the implications on the legality of these constructs under Danish law.

At the lecture to a group of Austrian students, Ms. Lykkeskov explained that various types of human-animal combinations have been created for decades although the moral or ethical implications have not been fully engaged with. This may be attributable to the formal distinction drawn between 'humans' and 'animals' in law, and at some point, legal change may be required to address the blurring of this distinction. Some of the Austrian students did not think that a formal change in law can resolve the underlying moral and ethical challenges that arise from compromised human dignity. The notion of 'dignity' is used extensively in European documents but its precise meaning is unclear. The ethical focal points that the councils identify as

376 *Ibid.*

377 Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo 4.IV, 1997).

underpinning human dignity do not differ in practical substance from the focal points of the NAS, CIRM, ISSCR and AMS, especially where they relate to human cognitive ability and human reproduction.[378] The AMS suggests that human form may also be an important way in which dignity is conceptualized.[379] In another European-based discussion on the subject known as the Chimbrids project, 'dignity' continued to be the key focal point.[380]

3.7 European Union

We became aware of the Chimbrids project, a two-year project funded by the EU under the Science and Society Priority 9 of the Sixth Framework Programme of Research for Structuring the European Research Area by Research on Ethics, through Professor Bartha Knoppers. Professor Knoppers was one of the members of this inter-disciplinary EU project team, set up to address questions that are expected to emerge from new technologies such as SCNT. The project deals only with human-animal chimeras and hybrids (not animal-animal chimbrids) and aimed to analyze fundamental problems in research that mixed human and animal materials in Europe and abroad.

The overall approach of the Chimbrids project team does not differ from those of policy bodies that we have considered in segregating issues in terms of science, ethics and law. There are a number of distinctive features in their published report (the "EU Chimbrids Report") however.

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[378] Danish Council of Ethics (with the Danish Ethical Council for Animals). *Man or Mouse: Ethical aspects of chimera research*. Copenhagen: Danish Council of Ethics, 2007, at 97-8.

[379] Academy of Medical Sciences. *Inter-species embryos*, London: Academy of Medical Sciences, June 2007, at 29.

[380] More information on the Chimbrids project is available at the following website: http://www.chimbrids.org/.

Most evident is the focus on key international or regional documents, rather than on expert guidelines such as those issued by the ISSCR (with the exception of the Declaration of Helsinki). Ethical and legal evaluation was mainly conducted within the analytical framework constituted by the Charter of Fundamental Rights of the European Union, the Council of Europe's Convention on Human Rights and Biomedicine and United Nation's declarations on human cloning and human rights. Apart from this, specific case studies are also considered in a cross-jurisdictional manner. Referred to as country reports, experts from Germany, the UK, France, Sweden, Spain, Austria, Switzerland, USA, Canada, Israel and Japan provided comments on ethical, regulatory and societal concerns arising from ten factual cases involving different research uses of human-animal combinations.[381] In addition, the report includes attempts to address more fundamental philosophical-anthropological questions (eg What does 'human nature' mean?).[382]

The outcome of an examination of scientific developments is a tabular matrix of the various types of human-to-animal and animal-to-human mixtures.[383] This matrix does not differ significantly from the one produced by the BAC in the early stages of its deliberation. This should not be at all surprising as information is essentially drawn from a common pool of scientific sources. In its ethical evaluation, the Chimbrids team continues to apply 'moral status' as its principal framework. The justification is drawn from a sense of inevitability as "it is impossible to genuinely avoid making decisions about the moral status of beings."[384] Under this approach, the features of sentience, rationality and autonomy, and species-membership have

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381 Jochen Taupitz and Marion Weschka (eds), *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009, Annex B (at 829 - 1030).

382 *Ibid*, at 17.

383 *Ibid*, at 57-8.

384 *Ibid*, at 62.

been identified as conferring human beings with moral status.[385] A similarly categorical approach was adopted in legal analysis. Moral status in ethics found equivalence in the notion of legal personhood – both arguably the legacies of the Enlightenment. Personhood is in turn the formal characteristic to which legal rights and obligations articulated in key European Union documents draw reference and attachment.[386] Even then, none of these documents provide a clear answer to the philosophical-anthropological issues at hand, other than reproductive cloning as the only exception.

On the issue of whether a human embryo, however derived, is a person (or 'everyone') under Article 2 of the *European Convention on Human Rights*,[387] both the European Commission of Human Rights and the European Court of Human Rights have indicated that the answer would depend on member states. In *Evans v. The United Kingdom*,[388] the European Court of Human Rights was not prepared to grant any rights to human embryos further than what the relevant national legislation was prepared to confer. Earlier on, the European Commission of Human Rights has expressed a similar stance in *H. v Norway*.[389] The contrasting national positions in Europe on this issue are well-know, with possibly the UK as among the most liberal, and Germany as among the most conservative, of the EU member states.[390] Similarly, the Council of

385 *Ibid*.
386 *Ibid*, at 88.
387 Council of Europe, *Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol 11*, CETS No. 005, Rome 4.VI, 1950.
388 European Court of Human Rights, Judgment of 7 March 2006, Application No. 6339/05, para. 46-47.
389 European Commission of Human Rights, Decision of 19 May 1992 on the admissibility of the application, Application No. 17004/90, Decisions and Reports 73, p. 155-171, 168.
390 Jochen Taupitz and Marion Weschka (eds), *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009, at 93.

Europe's *Convention on Human Rights and Biomedicine*,[391] as well as the *Additional Protocol on the Prohibition of Cloning Human Beings*,[392] does not define a 'human being' although it requires human dignity to be protected. Although 'dignity' is also not defined, Article 18(2) of the *Convention* prohibits the creation of a human embryo by fertilization for any research purpose. Whether this prohibition extends to a cytoplasmic hybrid embryo will depend on the significance attributed to the presence of animal mitochondrial DNA, and ultimately on the way in which an 'embryo' is defined.[393] The Chimbrids team notes that in Spain, an embryo or pre-embryo requires – by definition – the fertilization of an ovum. The biological construct of SCNT will not be an 'embryo' under this definition even though it will have all the features and potential of one.[394] Also relevant is Article 13 of the *Convention*, which prohibits any modification in the genome of any descendents unless undertaken for preventive, diagnostic or therapeutic purposes.[395] In addition, Article 1 of the *Additional Protocol* makes clear that reproductive cloning is a violation of human dignity and is thereby prohibited. As with the *Additional Protocol*, Article 3 of the EU's *Charter of Fundamental Rights* prohibits reproductive cloning as a violation of human dignity.[396] As for the status of a human embryo however derived,

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391 Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine – Convention on Human Rights and Biomedicine, European Treaty Series – No. 164, Oviedo 4.IV.1997.

392 Additional Protocol to the Convention for the Protection o Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, European Treaty Series – No. 168, Paris, 12.I.1998.

393 Jochen Taupitz and Marion Weschka (eds), *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009, at 109.

394 *Ibid*, at 107, footnote 199.

395 However, the Explanatory Report to the Convention indicates this provision does not apply to medical research involving genetic modification but not for the purposes of procreation: see paragraph 91 of Explanatory Report.

396 *Charter of Fundamental Rights of the European Union*, Official Journal of the European Communities 2000/C 364/01, of 18/12/2000.

the Chimbrids team indicates this is for member states to decide since Article 2 of the EU *Charter* corresponds to Article 2 of the *European Convention on Human Rights*.[397]

As we have seen, 'human dignity' is a notion central to European ethical and legal norms, and it is undoubtedly related to the ethical notion of 'moral status' as well as to legal personhood. Although not clearly defined, there are certain parameters entailed in the concept. We have seen that reproductive cloning and germline genetic modification (with limited exceptions) are two boundaries that should not be transgressed. Within the scope of activities that are permissible, we find a variety of policy orientations. The recommendations of the Chimbrids team are proposed from a more liberal standpoint, perhaps to maximize the policy options that are available to member states. However, chimbrids research should only be conducted following careful consideration of its scientific merit, human research ethics, animal ethics, legal aspects and societal and environmental implications.[398]

The specific recommendations set out in the EU Chimbrids Report do not detract from those of the other jurisdictions we have considered.[399] However, it is interesting to observe that while the Chimbrids team is similarly concerned with safeguarding human dignity, it seems to have adopted a position that is more liberal than that of the NAS in allowing the incorporation of animal pluripotent cells into a human blastocyst. On the issue of reproduction, the EU's position is similar to that of the NAS. Maintaining human dignity precludes the transfer of a human

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397 Jochen Taupitz and Marion Weschka (eds), *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009, at 111.

398 *Ibid*, at 456.

399 *Ibid*, at 457.

embryo into an animal and the transfer of an animal embryo into a woman.[400] Not surprisingly, a particularly striking feature of the recommendations in the Chimbrids Report is that there are at least five specific recommendations relating to reproduction and germline genetic modification.[401] This emphasis may be attributable to requirements under the Council of Europe's *Convention on Human Rights and Biomedicine* that we have considered.

3.8 Synthesizing an Approach

Prior to the public consultation, it was felt that the current system of review could be relied upon with some 'adjustments'. Under this system, IRBs will bear much of the burden in deciding if research involving chimeras and hybrids should proceed. However, the negative reaction that chimeras and hybrids invoked, especially among certain religious groups and some policy-makers, sent a clear message to the BAC that any research involving human-animal combinations could only proceed on a regulated basis. Yet even if regulation was to be introduced, a number of respondents in the public consultation have queried the credibility of institutional self-regulation. Still others observed that the current research governance framework did not extend to researchers working outside of a healthcare setting. These reactions contributed to a shift in policy orientation from self-regulation to a more stringent and pervasive regulatory approach. To better secure public confidence, assurance as to the effectiveness of any regulation when introduced was also considered to be necessary. In both these respects, the BAC looked to

400 *Ibid*, Recommendations 18 and 19 respectively.
401 *Ibid*, Recommendations 13 to 17.

the policies, proposals and experiences of other jurisdictions.[402] Throughout the process of policy formulation and discussion, the key documents that we have considered above have been important to the BAC's deliberations. These documents were exemplars of policy rationalities in the identification of ethical and regulatory issues, and in their resolution. Although these documents are context-bound, the rationalities, issues and goals have been generalizable and resonated with policy-makers in Singapore.

In the identification of ethical and regulatory issues, the documents of the NAS (along with ISSCR and AMS, as broadly sharing a particular ethical orientation), DCE and the EU Chimbrids project exhibited a degree of convergence. In essence, the integrity of two 'human' capacities was regarded as sufficiently fundamental to require regulatory safeguard. The first of these related to human sentience or consciousness, while the second was concerned with human reproduction. These concerns were similarly reflected in the feedback received by the BAC through its public consultation. To address these concerns, the BAC recommended that, for research involving chimeras, "particular attention should be paid to the need to avoid the creation of entities in which human sentience or consciousness might be expected to occur"[403] and that animals into which "any pluripotent stem cells have been introduced should not be allowed to breed"[404]. In relation to cytoplasmic hybrids, the substantive categorization of these biological constructs as effectively 'human' and thereby falling under the 14-day rule precludes concerns relating to human sentience or consciousness and reproduction from materializing.[405] For this,

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402 Paragraph 4.1 of the BAC's report on human-animal combinations clearly indicates the importance of regulatory experiences in a number of key jurisdictions. Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at 20.

403 *Ibid*, at 3, Recommendation 3.

404 *Ibid*, at 3, Recommendation 4.

405 *Ibid*, at 3, Recommendation 2.

the BAC has in effect adopted the rationale of the AMS, even in the absence of any legislative framework like that of the HFE Act.

Unlike the NAS, but similar to the ISSCR, the BAC did not consider it necessary to impose a moratorium over research involving (i) the introduction of any embryonic stem cells (human or non-human) into human embryos, and (ii) the introduction of human embryonic stem cells into non-human primate embryos. In relation to the first category, the ethical justification for this limitation was queried since there are potentially valid experiments that involve the making of human chimeras *in vitro*. For instance, they are useful in studying early gene activation. As for the second category, the introduction of a large amount of human cells into primates would be more contentious than creating human chimeras *in vitro*. This contention was felt not to be grounded in scientific logic, but on the perceived evolutionary proximity between humans and primates. It was also not entirely clear if primates were needed for such research at this time.

Unlike earlier discussions on regulatory framework, a national or central stem cell ethics review body to review all human embryonic stem cell research in Singapore, including research involving cytoplasmic hybrids and human-animal chimeras, was proposed for the first time.[406] The BAC explained that this was necessary "in the public interest to provide clear and comprehensive legal guidance that explicitly addresses the subject of research involving human-animal combinations".[407] Apart from this, IRBs have indicated that they do not have the necessary expertise to review research relating to embryonic stem cell research. Individual IRBs that currently provide oversight for stem cell research are not composed of people with the

406 *Ibid*, at 3, Recommendation 1.
407 *Ibid*, at 22, paragraph 4.10.

relevant expertise. It was envisaged that this national ethics review body will be composed of members with the relevant expertise. In addition, given Singapore's small size relative to larger countries like the US, centralization of such a review mechanism makes better sense than to implement a dual system of review (as proposed by the NAS). It was also felt that standardization through compliance with a set of national guidelines would minimize bureaucratic paperwork and ensure consistency in the ethics review process. Such a scheme would also be consistent with the ISSCR's recommendation for such an ethics body to be configured to suit the circumstance of each country.

In summary, the national stem cell ethics review body should ensure that there is evidence that the cell lines are from a reliable source and have been derived ethically (with documentation of the use of an IRB-approved informed consent process, etc) and that it complies with any additional review by an institutional animal ethics committee, an institutional biosafety committee and/or other institutionally mandated review.[408] As this area of research was considered to fall under the broad category of human embryonic stem cell research, the conscientious objection provision that was initially set out in the Stem Cell Report has been re-stated as a recommendation.[409]

[408] *Ibid*, at 22-23, paragraph 4.11.
[409] *Ibid*, at 3.

3.9 Policy Construction of a Limited Anthropology

Although it was not the intent of the BAC to posit any definition of 'human being', the recommendations of the HA Report ironically had this effect, albeit a limited one. Drawing on discourses in science, ethics and law, and in un-orchestrated synchrony with other policy bodies, the HA Report similarly identifies certain 'focal points' as essential characteristics of a 'human being'. These could be generally set out as (a) consciousness (as manifest in language, culture and religion) and sentience, (b) reproduction, and (c) human form, gestures and mannerism. These 'focal points' objectify the 'human being', through identification of the qualifying features for species membership, and also through objectification of the 'other' in chimeras and hybrids. These biological constructs have been the subject of all the documents considered. They all share a similar context in human stem cell research, and rely on – as justificatory rationale – a notion of 'common good' (to be discussed below) grounded in the belief that human welfare would be greatly advanced if knowledge of nuclear reprogramming could be perfected and applied. In all the documents considered, reliance on the triad of science, ethics and law in policy construction seemed almost programmatic. To borrow the language of Carol Heimer, this could well be taken as the cognitive structure that has enabled a particular construction of the 'human being' to be advanced in public policy.[410]

This cognitive structure that the policy documents appear to share places considerable emphasis on the empirical grounding of ethics and law, essentially by interpreting chimeras and hybrids as first and foremost scientific materials. We know, as a matter of scientific knowledge, that a

[410] Carol A. Heimer, Conceiving Children: How Documents Support Case versus Biographical Analyses. In Annelise Riles (ed), *Documents: Artifacts of Modern Knowledge*. Ann Arbor: University of Michigan Press, 2006, pp 95-126, at 121. In her study of documents in neonatal intensive care units, Heimer observes (at 121).

viable organism can be produced from mixing human and nonhuman materials, as well as the reasons for doing so. We also understand from the scientific community that biology cannot at the present time tell us what it is that makes us distinctively human – not in a material sense at least. From the human genome map, we learn that much of our genetic makeup is not extremely different from animals, lending some support to Darwinian postulation of evolutionary continuity. One could perhaps draw broad postulations on what 'humanness' amounts to on the basis of scientific knowledge alone, but this would be inconsistent with the character of science. Stem cell scientists work in the particular, and their preference is not to generalize. This has been my impression in attempting to get feedback from stem cell researchers and subsequently meeting with them. Dr. Munn relates a similar experience in that scientists "like to use a lot of caveats".[411] What they can tell us is that a human being is more than the sum of its material parts. Quite understandably, if chimeras and hybrids are biological 'tools' for researchers, their meaning will depend on usage.[412]

As we have seen, human stem cell research is the critical context for the policy documents that we have considered. It serves the dual function of enabling practical scientific definitions for chimera and hybrid to be formulated, and of securing legitimacy for research that will not yield immediate benefits. This may appear to be an obvious point, but it took some time for this association of object with context to sink in, perhaps due in part to the complexity of the artifacts and their distinct treatment in a separate report. Hence it was necessary for the HA Report to make clear in its title that the context remains as human stem cell research. It is here that policy

411 Interview with Dr. Helen Munn, 1 April 2008. Dr. Munn points to page 7 of the AMS report as illustration.

412 Phillip Karpowicz, Cynthia B. Cohen and Derek van der Kooy, It is ethical to transplant human stem cells into nonhuman embryos, *Nature Medicine* (2004) 10, 4: 331-5, at 331.

documents serve as a specific technology that enables comprehension through definition of context and focus.

Even working within specific settings or relatively more limited discourses, scientists are unable to agree on the likely impact or scientific merit of implanting human pluripotent cells into primates, for instance. As we have seen, the NAS, the NIH and the CIRM (basically, the major stem cell research institutions in the US) disallow the implantation of such cells into primate embryos. In contrast, the AMS, possibly the DCE, the EU Chimbrids team and the BAC do not consider this to be an issue provided that the 14-day or equivalent rule is applied. Arguably, this issue is likely to be more consequential in ethics than it is in science. On this point, Phillip Karpowicz *et al.* do not think that introduction of human neural stem cells into a primate will confer it with human cognitive ability as neural cells proliferate at different rate depending on the host environment.[413]

David Degrazia argues that it is insufficient to limit our analysis of 'humanness' to the material aspects or to 'cognition' as a physiological and psychological trait. In order to safeguard dignity, it is necessary to inquire into what 'personhood' entails. The term 'person' does not mean human being' or even "human being [with certain capacities]".[414] 'Person' is not merely descriptive, and thereby limited to certain capacities, but also prescriptive or moral. He explains that 'personhood' is "associated with a cluster of more specific properties without being precisely analyzable in terms of any specific subset: autonomy, rationality, self-awareness, linguistic competence, sociability, moral agency, and the capacity for intentional action. Not all of these

413 *Ibid*, at 334.

414 David Degrazia, Human-Animal Chimeras: Human Dignity, Moral Status, and Species Prejudice. In *Metaphilosophy* (2007) 38, 2-3: 309-329, at 319.

properties are strictly necessary for being a person."[415] On this basis, he argues that a 'person' is sufficiently constituted by "a being with the capacity for sufficiently complex forms of consciousness (each of the properties representing a form of consciousness)."[416] By this analysis, Great Apes are viewed as falling in a 'grey zone' between humans and animals,[417] and should have a moral status that is higher than rodents.[418]

The notion of 'personhood' has in fact developed over time. More than ten years ago, the same question was asked of human embryos. There was a single 'focal point' in the 14-day rule, in that an embryo (or 'pre-embryo') prior to having developed a 'primitive streak' is incapable of sentience. It is as such no more than a cluster of cells. Some people consider the 14-day rule to be arbitrary and hence incapable of acquiring ethical stature for the lack of rational basis.[419] However, Mary Warnock puts to an biological basis for this rule.[420] The 14-day rule has justification in that it is at approximately this stage of development that an IVF embryo would be implanted.[421] As such, the rationality of the 14-day rule is derived not from pure logic and theory, but an empirical basis and the practicality of technology. It is from this 'focal point' of when sentient life begins that the broader notion of 'personhood' is derived. At least one 'focal point' – that of consciousness – has a material source, and this is supplemented by other prescribed 'focal points'. In other words, chimeras and hybrids would not have had the meanings that they now do without the groundwork laid by the SC Report. Hence, the argument I am

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415 *Ibid*, at 320.
416 *Ibid*.
417 *Ibid*, at 322.
418 *Ibid*, at 326.
419 Interview with Professor Daniel Wilker, 10 May 2009.
420 Mary Warnock, *Nature and Mortality: recollections of a philosopher in public life*. London and New York: Continuum, 2003, at 95. She also points out (at 83) that "[m]ost people thought of the early embryo as a tiny homunculus, recognizably human."
421 Robert Winston, *A Child Against All Odds*. Reading: Bantam Books, 2007, at 42.

making here is that the policy epistemology of 'humanness' is incremental and contingent. It is characterized by 'focal points' that are in turn mapped onto broader scientific, ethical and/or legal discourses. In themselves, these 'focal points' are without meaning and could be regarded as arbitrary. But when linked to broader discourses and placed in context, they achieve a level of coherence that enables comprehension and justification. We see a parallel in the incremental manner in which scientific knowledge accrues. A stem cell researcher tells me that knowledge of nuclear reprogramming from SCNT did in fact enable the development of iPSC technology.[422]

These 'focal points' resemble what Bruno Latour labels as "circulating reference".[423] The concept of human-animal combinations could be in some ways seen as derived from similar notions that were circulated along the "reversible chain of transformations,"[424] which one could read as a reversible chain of documents. In this connection, the HA Report could be perceived as a link in this 'chain'. While the link possesses certain features that are distinctive to Singapore, it exhibits a cognitive structure, or "already-established centers of calculation", that would enable its identification and application outside of the local context. Even so, it would be imprudent to gloss over the fact that these 'focal points' are embedded within a particular cognitive structure and are developed within specific time and space to deal with particular challenges.

Whereas the NAS, AMS and BAC appeared to have relied on science as an analytical starting point, the DCE and the EU Chimbrids project group were somewhat more predisposed to assuming a stronger ethical basis in the science-ethics-law cognitive triad. In Denmark and in the

422 Interview with Dr. Pauline Tay, 18 August 2009.

423 Bruno Latour, *Pandora's hope: Essays on the reality of science studies*. Cambridge MA: Harvard University Press, 1999, pp 24-79 (Circulating Reference: Sampling the Soil in the Amazon Forest), at 24.

424 *Ibid*, at 71.

EU Chimbrids project, deliberations have largely been centered around the notion of 'dignity' as articulated in key European documents. In the case of Denmark, less reliance on institutional-based review may have affected the way in which the DCE thought about the appropriate set-up for ethics review. Like the NAS, the deliberations of the Chimbrids project team are more generic and broad. Its conclusions do not significantly detract from those of the NAS but there is substantial focus on human reproduction and germline genetic modification. These may in turn be traced back to the ways in which 'dignity' is construed. Drawing from ethical and social theories, Christian Smith argues that humans possess an inherent dignity by virtue of "the kinds of creatures they are ontologically".[425] He considers this to be real and objective in that it is not culturally relative or conferred upon by social contract or positive law. It is not an institutional fact or a social fact, but a "brute fact" of ontological reality.[426]

In essence, Smith proposes that human persons are ontologically real and causally capacitated, but not autonomous or self-sufficient. Social construction depends on our capacities of personhood, and the former in turn help to define and sustain our durable identities, moral commitments and social communications.[427] He argues that humans are naturally highly capacitated and these capacities entail natural structures, directions and limits.[428] However, the knowledge that arises from these capacities (such as language, which he considers to be enabling rather than limiting) is always human and personal knowledge. It is subjective unless

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425 Christian Smith, *What is a Person? Rethinking Humanity, Social Life, and the Moral Good from the Person Up*. Chicago and London: University of Chicago Press, 2010, at 434. In analytical approach, he proposes a critical realist personalism as a third way between materialism, which he considers to ignore meanings, language, and interpretation, and strong form social constructionism, which conflate reality into meaning, language, and interpretation (at 198). Materiality is constituted and governed by natural laws of existence and function – what the hard sciences relate to (at 169).

426 *Ibid*, at 444.

427 *Ibid*, at 197.

428 *Ibid*, at 173-179.

institutionalized or otherwise related to an ontological reality.[429] Smith observes that human dignity is real at an institutional level. However, he assumes that whether language or knowledge, they accurately map onto an ontological reality, and does not quite explain how this 'overlap' between social construction and 'reality' maps onto each other, and to what extent. In relying on a cognitive structure composed of the science-ethics-law triad, the policy (and policy-related) bodies that we considered have drawn on all three institutions in the crystallization of the 'focal points' that would objectify the 'human being'. The 'focal points' have in turn been associated with or otherwise subsumed within the broad notion of dignity, providing much needed vigor to both. On their own, these 'focal points' are matters-of-fact that lack moral force. In contrast, human dignity in some form or other has moral persuasion but is often devoid of substantive and practically useful content. Collectively, these policy documents on hybrids and chimeras have united 'focal points' to dignity in the context of human stem cell research and under a justificatory analytic of the 'common good'.[430] In addition, by way of recourse to science, ethics and law, the 'overlap' is essentially assumed, to the extent that all three institutions represent varying degrees of 'naturalness' or 'found-ness' in nature, the right and order. From a more pragmatic standpoint, the presence or absence of an overlap is perhaps not important given that a notion of dignity has been implicitly or explicitly subscribed to in all of the policy documents considered.

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429 On this point, Smith observes: "There is not Universal, Generic Knowledge out there for us to acquire. There is rather for humans only human knowledge – knowledge fitted for and appropriate to humans as particular beings. There appears to be other kinds of knowledge that are not human knowledge…bats possess "bat knowledge" of reality…" *Ibid*, at 180.

430 The Warnock Report has itself resorted to claims of naturalness in conceptualising the family and parenthood. See Fenella Cannell, Concepts of Parenthood: the Warnock Report, the Gillick debate, and modern myths, *American Ethnologist* (1990) 17, 4: 667-686; and Peter Rivière, Unscrambling Parenthood, *Anthropology Today* (1985) 1, 4: 2-7.

Still, the anthropology that has emerged in these policy documents is limited and fragmentary. In other words, we still do not quite know what is essentially 'human' from a non-anthropocentric point of view – if this vantage point can be assumed at all. As Annelise Riles has noted, policy documents are often less interested in expounding concepts or terminologies (such as 'women' in her study) than they are in ensuring institutional continuity.[431] Nevertheless, this minimum content has been sufficient in expunging hybrids and chimeras from the sanctity of human dignity, as the 'other'. In other words, a moralistic and naturalistic viewpoint that human beings belong to a higher moral order is sustained. Humans are self-aware, cultural, spiritual and capable of complex reasoning; not animals. The sacred is again clearly demarcated from the profane.[432] The cognitive structure thereby confers legitimacy through analogies that further entrench the perceived distinctions between humans and nonhuman animals. The reports that include substantive discussions (i.e. those of the NAS, AMS, DCE, EU Chimbrids project and BAC) all indicate that various forms of human-animal combinations have been useful to humanity for a long time. There is as such nothing unusual or detrimental about continuing to work with chimeras and hybrids under controlled conditions and for socially beneficial reasons. In *We Have Never Been Modern*, Bruno Latour observes that science has created a whole range of hybrids, or 'quasi-objects' which are neither merely natural things nor people or subjects.[433] But even though scientists have been creating these hybrid beings, people have denied this hybridity and preferred to demarcate 'nature' clearly from 'society'.[434] He thus surmised that

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431 Annelise Riles, *The Network Inside Out*. Ann Arber: University of Michigan Press, 2001, at 80-81. At page 80, she observes: "For example, if one takes the general subject of this conference "women," certainly the word *women* appeared frequently enough in the thousands of documents that circulated through the meeting. Yet in practice, it was hardly clear what this word "meant" at all and how it might be delineated by the scope of other UN conferences on subjects such as development, human rights, population, children, or environment."

432 Emile Durkheim (translated by Karen E. Fields). *The Elementary Forms of Religious Life*. New York: The Free Press, 1995 [1912], at 34.

433 Bruno Latour, *We Have Never Been Modern*. New York and London: Harvester Wheatsheaf, 1993 [1991], at 6.

434 *Ibid*, at 10.

"[w]e have never plunged into a homogeneous and planetary flow arriving either from the future or from the depths of time. Modernization has never occurred."[435] Yet Latour is aware that difficult political issue would arise if we take up the challenge of constituting a 'Parliament of Things'. The present scenario illustrates the institutional constraints in accommodating certain nonhuman animals as 'humans' or like-'human', let alone as a category that is neither 'human' nor 'animal' (ie 'thing').

3.10 The 'Common Good'

A contact told me over lunch that some year back, she decided not to pursue a career as a research scientist in spite of having had post-graduate training. In order to excel and ultimately become a Principal Investigator, you will have to "ask the right questions".[436] I pursued the point further, and learnt that a Principal Investigator must not only be able to carry out scientific experiments that answer issues of relevance to science, she must also ensure that they are of interest to funders. If we assume for simplicity that society follows ethics, then difficulties could arise when the questions that scientists are interested in do not conjoin with those of ethics. In a lecture at Raffles' Girls School – one of the most prestigious secondary schools in Singapore, a student asked what the scientific criteria for 'humanness' are.[437] It is I think a fair question as one might expect science to provide useful insights. It was also one of the questions that I had in mind when I first began research on the subject of human-animal combinations. This question was directed to Professor Davor Solter, one of the foremost stem cell researchers, who worked in

435 *Ibid*, at 76.
436 Fieldnotes, 17 July 2008.
437 Fieldnotes, 3 October 2008.

Germany and the US before coming to Singapore. In response, he said that while biology may point to some important differences between human beings as a species from some other species, ultimately the question of 'humanness' is not one that scientists regard as meaningful to pursue. He queried: "When does a grain of rice become a pile of rice?" It could be an interesting ethical question, but he considered it to be a waste of time for scientists to work on when an organism becomes 'human'. He observed that if half of all the cells in a mouse is composed of human cells but looked and behaved like a mouse, it would not be regarded as 'human'. Even if an animal has a human organ, it would still not be regarded as an animal. At this point, I am reminded of my conversation with Professor Martin Bobrow at the start of my research. He shared a similar view in that the issue of "what makes a human" is a philosophical question and cannot at this point be answered by biology. Hence, he said in a half-joking manner that a pragmatic test to go by could be formulated as:[438] "If it [the chimera or hybrid] walks past you in the street and you say it is 'human', it is 'human'. It is a little like a jury trial." As we have seen, this also appears to be the position of NACLAR. In follow-up interviews that I conducted with stem cell scientists, their remarks are similar to those noted by Michael Gazzaniga:[439] "A cell is a cell is a cell. It's a universal unit of processing that only scales in size between the bee and the human…There are differences in the types of neurons within a brain, and response properties of neurons within a brain. But across mammals – I think a neuron is a neuron."

It seems clear that if one attempts to search for a fundamental divide between humans and nonhuman animals, the answer will not (or not completely at least) be in biology. Jason Robert and Françoise Baylis agree that there is no sharp biological division between humans and

438 Fieldnotes, 25 September 2007.

439 Michael S. Gazzaniga. *Human: The science behind what makes your brain unique*. New York: HarperCollins Publishing, 2008, at 8.

animals. Any feeling of abomination or disgust towards the creation of interspecies organisms is a moral and social construct.[440] They agree that it is erroneous to think of species identities as fixed and that, by virtue of this putative fixity, there is a scientific, political and moral imperative to protect and preserve the integrity of human beings and the human genome. However, they consider the most plausible objection to the creation of such creatures to rest on the notion of moral confusion, in that "countless social institutions, structures, and practices depend upon the moral distinction drawn between human and nonhuman."[441] Chimeras and hybrids could undermine moral and social order as it forces one "to confront the possibility that humanness is neither necessary nor sufficient for personhood."[442] In the previous chapter, we have seen how the fundamental divide between humans as *persona* and animals as *res* is sustained by treating human-animal combinations as *res*. If Jacque Derrida is right that there is something ontological about shame in human consciousness that necessitates this aggression towards our "other" in nonhuman animals,[443] it is certainly not the place for a policy paper to fundamentally reconfigure the existing moral and social order. In this sense, law and ethics have served as a means by which moral and social orders have been adjusted to accommodate a novel construct of science.

Professor Bobrow provided me with a helpful lead in his indication that while there is no standard definition of 'humanness', certain traits are associated with being 'human'. Human consciousness, reproduction and form have all been identified as demarcating features. For instance, the public would understandably be alarmed if a chimeric mouse started to walk around

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440 Jason Scott Robert and Françoise Baylis, Crossing Species Boundaries, *American Journal of Bioethics* (2003) 3, 3: 1-13, at 8.

441 *Ibid*, at 10.

442 *Ibid*.

443 Laurence Simmons, Shame, Levinas's Dog, Derrida's Cat (and Some Fish). In Laurence Simmons and Philip Armstrong (eds), *Knowing Animals*. Leiden: Brill, 2007, pp 27-42. Simmons uses Derrida's critique of specieism to show the ontological basis of shame in human consciousness.

like a human being. The risk of this occurrence is low since the objective of stem cell research is not to confer human traits on non-human animals. To understand the creation of human-animal combinations in terms of its research end goals suggests that it is possible to move forward with regulatory policies on chimeras and hybrids without having to determine what makes us 'human'. The end goals of stem cell research are clear and, as we have considered in Chapter 1, supported by some level of public opinion. Concern over the moral status of an embryo has to some degree been answered in the artifact of the 'pre-embryo'. Legal pragmatism in particular, came to mind. Justice Cardozo wrote some time back:[444] "There had arisen a new situation which could not force itself without mutilation into any of the existing moulds. When we find a situation of this kind, the choice that will approve itself to this judge or that, will be determined largely by his conception of the end of the law, the function of legal liability; and this question of ends and functions is a question of philosophy." A more recent manifestation of this pragmatism at law is evident in the decision of *In re A*.[445] The issue before the court was whether Jodie and Mary as conjoined twins should be separated since separation would inevitably cause Mary's death. If not separated, both Jodie and Mary would die. The parents were unable to consent to the operation as they sincerely believed – being devout Roman Catholics – that the twins were equal in value and it would be against the will of God to kill one in order to save the other. Relying on medical evidence that twins have distinct individuality, Lord Justice Ward held that twins could be separated, thereby also sidestepping the controversial and indeterminate question of the personhood of an embryo or a fetus.

444 Benjamin N. Cardozo, *The Growth of Law*. New Haven: Yale University Press, 1924, at 101.
445 *In re A* [2000] 4 All E.R. 961.

Purely intellectual pursuit is a luxury in policy work. Due to constraints of politics, resources and time, difficult policy issues require judgment based on public standards and morality.[446] Dame Mary Warnock expresses this sentiment when she chaired the *Committee of Inquiry into Human Fertilisation and Embryology*. She was motivated to assume the role by her intellectual interest in the subject (which includes the relationship between law and morality), but ultimately concluded that two years was too short a time for serious intellectual engagement. For her, as it has been for me, time is itself an epistemological frame – albeit in the manner of a constraint – and more importantly, an assurance of currency and relevance.[447] Ethical reasoning has provided a basis by which stem cell research involving chimeras and hybrids could proceed. Regardless of whether one considers the ethical premises to be morally right, it was necessary for arguments raised in the BAC's documents to be acceptable. My experience in public policy work on stem cell research is consistent with the observation of Dame Warnock that what is considered to be morally right should be distinguished from what is acceptable.[448] The constraints that time and other factors imposed require a focus on what is acceptable as a matter of public policy. As Dame Warnock then explains, what is "acceptable" often depends on what is believed to advance the common good of society.[449]

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446 Ronald Dworkin, *Law's Empire*. Cambridge MA: Harvard University Press, 1986, at 256. Dworkin argues that law as integrity requires a judge (ie Hercules J) to choose between eligible interpretations by asking which shows the community's structure of institutions and decisions – its public standards as a whole from the standpoint of public morality.

447 Mary Warnock. *Nature and Mortality: recollections of a philosopher in public life*. London and New York: Continuum, 2003, at 104: "What's so sacred about June 26th?" This was the day which the committee has agreed to hand over the report, the press conference had been called and "everyone had adjusted their diaries".

448 *Ibid*, at 98-99.

449 *Ibid* at 100.

Annelise Riles makes a similar observation. In her study of the United Nations' Fourth World Conference on Women, Riles observes:[450] "If the chair's authority was always contentious, the authority of time went unquestioned." In order to achieve 'progress', 'gender' as a central subject matter was not finally addressed, but an acceptable document was produced.[451] Charles Yablon argues that court judgments are no different in that they present what is considered to be acceptable rather than what is true or right.[452] Crafting the BAC's documents was made easier by the fact that there is a notion of 'common good' under the broader discourse of stem cell research. Consequently, the emphasis was on explaining and justifying proposed courses of action that are likely to advance the 'common good', which in this case continues to be centered around the hope of regenerative medicine. In the previous Chapter, we looked at how the metaphorical content of chimeras and hybrids was reconstituted in terms of certain ethical, scientific and social goals and specifications. The involutionary process was a means of rationalizing and systematizing a social phenomenon through the construction of hierarchical categories. Legal objectification was a means of explaining and justifying a regulated approach, very much in the spirit of the SC Report. As we have seen, it has been relatively effective in meeting particular policy objectives, essentially by rendering visible and calculable certain concerns as regulatory risks. The drive to explain and justify also necessitated the search for allies. The rationale was that the more one's position is shared by others, the greater the sense of 'common good'.

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450 Annelise Riles. [Deadlines]: Removing the Brackets on Politics in Bureaucratic and Anthropological Analysis. In Annelise Riles (ed), *Documents: Artifacts of Modern Knowledge*. Ann Arbor: University of Michigan Press, 2006, pp. 71-92, at 86.

451 *Ibid*, at 87.

452 Charles M. Yablon , Are Judges Liars? A Wittgensteinian Critique of Law's Empire (1990) 3 *Canadian Journal of Law and Jurisprudence* 123, at 124-5, and 135-8.

3.11 Global Script(s) on Hybrids and Chimeras

In their study of the impact of international institutions on lawmaking in China, Indonesia and Korea over a period of 15 years, Terence Halliday and Bruce Carruthers argue that the globalization of bankruptcy law has proceeded through recursive or iterative cycles at three levels: national, global and intermediate.[453] Recursive cycles could be relatively simple or highly complex:[454] "The simplest patterns stay within cycles of a particular kind of law: an iteration from statutes to practice to amended statutes, or from court decisions to practice to further decisions, or from regulations to compliance to further regulations. More complex cycles can take several forms…[where] earlier states in a cycle, or even earlier cycles, produce momentum that constrains the direction and impact of subsequent lawmaking and implementation." Drawing on Lauren Edelman's theory of the endogeneity of law in national lawmaking as involving endogenous actors and mechanisms, they consider recursivity to be a better account of legal change as a dynamic and inclusive process, where new law arises less from lawmaking bodies and more from sites of practice, especially corporations.[455] This endogeneity of law is regarded as "a special instance of recursivity" in that it "incorporates full cycles of change from one kind of law (statutes) through creation of another kind of "law" in practice through to its institutionalization via judicial rulings (case law). It has something of the invisibility of legalistic reform for it unfolds far from the interest-group hurly-burly of legislatures and more through the technical advances negotiated among human resource experts, lawyers, and judges." In national

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453 Terence C. Halliday and Bruce G. Carruthers, The Recursivity of Law: Global Norm Making and National Lawmaking in the Globalization of Corporate Insolvency Regimes, *American Journal of Sociology* (January 2007) 12, 4: 1135-1202. In this paper, the model of recursivity proposed is considered to be an approach to legal change that is "dynamic, evolutionary and nested": *Ibid*, at 1192.

454 *Ibid*, at 1144.

455 *Ibid*.

lawmaking, endogenous change is attributed to the continuous interactions between actors and mechanisms in lawmaking and implementation,[456] which could otherwise be articulated as an interaction between formal law (statutes, cases and regulations) and law in practice (institutional behavior). Experiences in national lawmaking, as Halliday and Carruthers observe, frequently influences global norm making through exogenous actors (such as international financial institutions, governance organizations and professional associations) and exogenous processes (which includes economic coercion, persuasion and modeling).[457]

As illustration of the constitutive power of legal concepts, Halliday and Carruthers point to global scripts that instantiate norms for adoption.[458] Elsewhere, they observe that, as different script producers were involved, several varieties of formalization could exist.[459] The various scripts could in turn be categorized into two main types: those that were descriptive or prescriptive codes (as represented by the IMF, World Bank, Asian Development Bank, and UNCITRAL (United Nations Commission on International Trade Law) documents), and those that were developed and used by international financial institutions and consultants as diagnostic tools.[460] These scripts emerged, following the Asian Financial Crisis in 1997. Consolidation followed when the UN articulated a single consensual norm in 2004, so that by 2005, all

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456 Four mechanisms that drive recursive cycles are identified as the *indeterminacy* of law, *contradictions, diagnostic struggles* and *actor mismatch*. *Ibid*, at 1149-1153.

457 *Ibid*, at 1148.

458 Norms are defined, for heuristic purposes, as "formalized codifications of behavioral prescriptions that are accepted by subjects as legitimate and authoritative." Terence C. Halliday, Recursivity of Global Normmaking: A Sociolegal Agenda, *Annual Review of Law and Social Science* (2009) 5: 263-289, at 268.

459 Bruce G. Carruthers and Terence C. Halliday, Negotiating Globalization: Global Scripts and Intermediation in the Construction of Asian Insolvency Regimes. *Law & Social Inquiry* (2006) 31, 3: 521-584, at 536.

460 *Ibid*, at 570-571. Variations in forms of global scripts related largely to the level of discretion that nation-states had in different analytical possibilities: *Ibid*, at 540.

countries in the region were expected to conform to this legitimated standard.[461] In her study of human rights abuses in Burkina Faso and Kenya, Sally Falk Moore has similarly alluded to the presence of a 'global script' in the form of universal standards of morality in international human rights instruments that enables local struggles to be mapped against. Hence she observes that "[w]orldwide connections are being created out of the episodes of local struggles. And those connections involve a common, diffuse, value-laden symbolic content, as well as implying that practice consequences may emerge for individuals, institutions, and organizations."[462]

However, it is unclear if there is uniform agreement over whether "global scripts" are intrinsic or otherwise necessary to processes of globalization, especially where the law is a contributory force. For instance, the existence of a similar "global script" is more ambiguous in Sally Engle Merry's study of the adoption of human rights interventions for gender violence. It is not entirely clear if there is an essentialized human rights content that could be appropriated, localized, transformed or otherwise imposed. For Merry, all script – if there is one – is neither 'local' or 'global' (but possibly 'glocal').[463]

Marina Kurkchiyan's study of the failure to set up UK-styled media self-regulatory bodies in two Russian cities, Rostov-on-Don and Nizhniy Novgorod, appears to support Merry's position. Referring to Douglas North's notion of institutions as "rules of the game", institutional transplant could be regarded as a means by which new rules (both formal and informal) are set for local

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461 *Ibid*, at 539. Between 1998 to 2005, Carruthers and Halliday observe four main phases (at 569-571): (1) multiple actors and no formal script; (2) multiple actors and multiple formal scripts; (3) competing scripts and actors leading to hybrid forms; and (4) multiple actors and a single script.

462 Sally Falk Moore, *Political Struggles in Legal Arenas: Some African Instances*. In Max Kirsch (ed), Inclusion and Exclusion in the Global Arena. New York: Routledge, 2006, pp 269-286, at 284.

463 Sally Engle Merry, New Legal Realism and the Ethnography of Transnational Law, *Law & Social Inquiry* (2006) 31, 4: 975-995, at 986.

players.[464] The attempt to introduce an ethical means of regulation failed when, as Kurkchiyan finds, the core concept (in the transplantation exercise) of moral or ethical restraint was immediately understood as (or perhaps replaced by) legal restraint.[465] Consequently, all media disputes were managed legalistically, in direct contrast to the original intent of a less formalistic approach in the Anglo-American system of alternative dispute resolution. Kurkchiyan explains that as "both the idea of industrial self-regulation and of mediation as a means of dispute resolution, more generally, were not part of the local know-how", these notions and related practices "had to be explained, understood, interpreted, and implemented from scratch".[466] The outcome of her research suggests that, in thinking about what got transplanted, the emergent set of thinking and practices were neither 'local' (in the sense of conventional Russian institutional practices) nor 'global' (in the UK-styled self-regulatory practices), but perhaps a hybrid of the two, at best. Otherwise, it is questionable if transplantation arose at all, if there has been no significant change in the dominant mentality in conventional Russian practices, albeit with some modifications.

At least initially, the documents of the NAS appears to have created a 'script' that is akin to a form of globalized localism. In the years between 2005 to 2010, we observe a similar recursivity described by Halliday and Carruthers in initial creation of the guidelines of the NAS, their endorsement by the ISSCR (albeit with some exceptions), and subsequent revisions made by both the NAS and ISSCR. Jenson and Santos define this process as one whereby certain local conditions succeed in traversing borders and so acquire the status of the 'global', either by

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464 Marina Kurkchiyan, Russian Legal Culture: An Analysis of Adaptive Response to an Institutional Transplant, *Law & Social Inquiry* (2009) 34, 2: 337-364, at 340.

465 *Ibid*, at 359.

466 *Ibid*, at 348.

constituting or otherwise by defining the dominant features of global consciousness on the subject. This status further enables it to designate rival conditions as local.[467] A similar, though possibly less recursive, process has been observed in Europe, mainly centered on the *Convention of Human Rights and Biomedicine*. However, we also do observe what Sally Engle Merry describes as indigenization, or localized globalism, which entails the selective adaptation of a global ideal to local conditions.[468] The approaches of the BAC, and to some degree, the AMS, bear features of indigenization to varying degrees.

Due to similar factors, it was found in another study that, together with greater mortality burden as an epidemiological condition, medical globalization resulted in greater global institutional heterogeneity across 58 countries.[469] The co-development of western allopathic medicine and traditional-alternative medicine did not support the homogeneity thesis in globalization literature, which quite understandably assumed substitution of the latter by the former given the dominance of the world polity of medicine by western-allopathic medical organizations. Much to the contrary, greater heterogeneity is perhaps to be anticipated with the expansion of the world polity of medicine to include other international agendas such as human rights and development. From the standpoint of the BAC at least, there were two 'global' scripts: one that could be traced to the NAS, and another to continental European sources. Developments in the UK were not quite of 'global' proportion, but important for reasons set out in the previous chapter and this. The point to be noted is that the diversity of 'globalization' experiences, including various theorized forms

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467 Jane Jenson and Boaventura de Sousa Santos. Introduction: Case Studies and Common Trends in Globalizations, in *Globalizing Institutions: Case Studies in Regulation and Innovation*, eds. Jane Jenson and Boaventura de Sousa Santos. Aldershot: Ashgate, 2000, pp 9-26.

468 Sally Engle Merry. *Human Rights and Gender Violence: Translating International Law into Local Justice*. Chicago: University of Chicago Press, 2005.

469 Jae-Mahn Shim, Gerard Bodeker and Gemma Burford. Institutional heterogeneity in globalization: Co-development of western-allopathic medicine and traditional-alternative medicine, *International Sociology* (2011) 26, 6: 769-788, at 781-782.

of institutional dynamics such as translation, isomorphism, decoupling and hybridization,[470] may well account for the diversity of what could be regarded as 'global scripts'. Yet, for various policy reasons that have been noted earlier, the BAC preferred a consolidated reading of these scripts, as a 'global' or 'international' script. This was possible as the 'focal points' advanced by these scripts shared the same placeholding notion of the 'common good' and were basically complementary.

3.12 Institutions and their Documents in Global Scripting

Globalization has been in a significant way an account of relationships. In 1974, Immanuel Wallerstein provided a macrosocial account of globalization as division of labor among different geographical regions and countries.[471] In essence, Wallerstein proposes a trimodal structure involving three regions: a core region of high-wage, capital intensive and skilled labor, a peripheral region focused on raw material production and intensive in unskilled labor, and a semi-periphery region with mixed forms of labor and capital intensity. In this world-system paradigm, Wallerstein attempts to describe how countries and regions compete to impose dominant cultures, which could be broadly understood as a system of shared meanings and symbols. His account has been criticized over time on a number of bases, including a lack of descriptive rigor due in part to its generality. In my view, William Robinson correctly observes that the notion of globalization depends very much on what we understand as being circulated in

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[470] Gili S. Drori, John W. Meyer, Francisco O. Ramirez, and Evan Schofer. *Science in the Modern World Polity: Institutionalization and Globalization*. Stanford, CA: Stanford University Press, 2003. See also Jan Niederveen Pieterse. *Globalization and Culture: Global Melange*. Lanham: Rowman and Littlefield, 2004.

[471] Immanuel Wallerstein. *The Modern World-System I: Capitalist Agriculture and the Origins of the European World-Economy in the Sixteenth Century*. New York: Academic Press, 1974.

global systems.[472] In analyzing global scripting on hybrids and chimeras, what captivated me was the circulation of policy documents and the 'focal points' that they encapsulated, not quite that transnational capitalist class that Robinson points to.[473] Again, 'focal points' seem appropriate as the process of policy development was focused on (primarily 'local') coordination, but not in a planned or orchestrated way. In addition, there did not appear to be an explicit agenda of network building or network power,[474] although earlier attempts to create international norms on human embryonic stem cell research did. The global scripting process, in the initial stages at least, appeared to be more happenstance, where the circulation of normative frames and norms, as well as sense-making endeavors, was made manifest in the exchange of policy documents.

It is further important to recognize the role of institutions as 'script carriers'. In a study on the attitudes towards, and the practice of, female genital cutting in five African countries, it was found that institutions that carry 'modern' scripts all reduce the probability that women will favor the continuation of 'circumcision' of their daughters.[475] Adopting a neoinstitutionalist approach, 'modern' institutions such as education, college, mass media and employment, have been identified as "script carriers"; they provide institutional logics that could be drawn upon for

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[472] William I Robinson. Globalization and the sociology of Immanuel Wallerstein: A critical appraisal. *International Sociology* (2011) 26, 6: 723-745.

[473] *Ibid*, at 741.

[474] David Singh Grewal similarly draws on Thomas Schelling's notion of 'focal points' in analyzing network power. However, the networks that he addresses appear to me to be constituted by relatively fixed or structured relationships. Zeev Maos presents a similar (although significantly more quantitative) analysis of network relations. I did not find rigid or structured relations among the institutions that I have studied. The representatives from these institutions whom I interviewed similarly did not consider their various institutions to be part of a 'network'. Neither the NAS nor the CIRM, which shared close working relationships on a number of projects, considered themselves to be associated in this way. David Singh Grewal, *Network Power: The Social Dynamics of Globalization*. New Haven and London: Yale University Press, 2008; and Zeev Maoz, *Networks of Nations: The Evolution, Structure, and Impact of International Networks*, 1816-2001. New York: Cambridge University Press, 2011.

[475] Elizabeth Heger Boyle, Barbara J McMorris and Mayra Gomez. Local Conformity to International Norms. *International Sociology* (2002) 17, 1: 5-33.

constructing individual identities and understandings about the world.[476] Modernization is thereby seen as a process of reshaping an individual's entire cultural universe, and not just perspectives in 'modern' environments. Adding to this, a materialist element was also noted as a contributing factor. Professionalized international governmental organizations and international non-governmental organizations with relatively large amounts of resources have played a prominent role in the neo-institutionalist account of how changes have occurred through globalization.

Documents are artifacts of (post?)modern knowledge in that they are relational, not so much in and of themselves, but as an essentialized component of their originating institutions – the 'script-carriers'. At one level, they mediate relationships within institutions. In sending the HA Consultation Paper and receiving feedback in return, the BAC establishes a relationship with its consultation party. The act of giving a document creates an information potentiality that motivates contact. The very construct of ethical or legal rules has the effect of enjoining the public, the state and researchers in a three-way relationship. Sarah Franklin and Celia Roberts liken this to a social contract. They argue that the "Warnock strategy" entails a certain "give-and-take" such that in exchange for permitting a limited amount of embryo research, the state would assure the public of strict regulation that is subject to the very highest standards of public accountability. It was in this context that Mary Warnock posed a question about feeling, judgement and belonging to which she offered a solution of tolerance, compromise and

[476] *Ibid*, at 6-7 and 25-26. Neoinstitutionalism and modernism are regarded as differing from each other in the former's emphasis on international systems and scripts, whereas the latter focuses on individual-nature relationship.

regulation.[477] In creating a sense of a whole that is greater than the sum of its parts, a kind of "social contract" emerges that marks the "British way forward" with techniques such as PGD and IVF, as well as with human cloning, stem cell technology and biobanking. Franklin and Roberts allegorizes this as a firm hand that disciplines the troops, so that if discipline and order can be maintained, much faster progress will be made – to everyone's benefit.[478] The 'common good' is thus actualized and lived. In addition, these documents put forward various forms of orderings and co-ordinations. We can broadly group them as institutional-based review (NAS, NIH, CIRM), centralized regulation (DCE, EU Chimbrids project), and mixed approaches (AMS, ISSCR, BAC). Such social configurations lower uncertainty as to how scientists are expected to behave and how the public would (and should) react. They confine the conduct of scientists to what is permissible and assure the public that scientists will conform to these prescriptions. What was unpredictable is now within expectation.

In considering and adopting some of the 'focal points' in the *NAS Guidelines*, the BAC and the NAS became 'related' by commonality. In contrast to this analysis, the notion of 'circulating references' suggests that there is some form of collective effort at developing 'focal points'. While this may be the case in certain situations, I have not found any conscious effort toward collaboration as such. One institution borrows from another to a degree, but the concerns that each institution sets out to address is uniquely its own and often peculiar to its time and context. But as we have seen, this does not mean that there is no commonality. The indebtedness is often paid towards the advancement of commonalities and arguable *is* the cause of social relations. It is one reason why the BAC is concerned with developments that occur outside of its territory, and

[477] Sarah Franklin and Celia Roberts. *Born and Made: An Ethnography of Preimplantation Genetic Diagnosis.* Princeton, NJ: Princeton University Press, 2006, at197.

[478] *Ibid*, at 198.

vice versa. In addition, documents are a basis of (or trigger for) institutional learning. They are also means by which various knowledge systems 'come together' in the production of a 'collective consciousness' of sorts, or perhaps a discourse among discourses – a very generic 'global script'. In legal analysis, it is akin to the association of cases through the derivation of their respective *ratio decidendi*.

The documentary bases upon which these 'focal points' subsist should not be overlooked. The documents of the institutions that we have considered all embody the essence of their respective institutional sponsors and thereby have meaning quite apart from the broader socio-political climate. They are, in a sense, samples of Weber's basic model of society; that is an equilibrium between different institutional sectors taken on a global scale.[479] In their portrayal of what constitutes human and non-human, these documents enable us to learn about ourselves from the societies they represent, in the way that perhaps Durkheim's idea of *anomie* in his book on suicide does.[480] The HA Report is indebted to a number of other documents in the development of an ethical framework that is relevant to the subject of human-animal combinations. The exchange or linkage of documents does not necessarily point to the existence of social relations. It does however signify some level of shared consciousness, an intersubjective space.

The 'focal points' are means by which this intersubjectivity is accessed. As we have seen, documents are communicative in the substantive information that they embody. In addition, they are instruments by which discursive and normative categories, as well as practices, are de-constructed, created or sustained. Looking into a document, we find that texts are social facts in

479 Mary Douglas. *How Institutions Think*. Syracuse: Syracuse University Press, 1986, at 93.
480 *Ibid*, at 97.

that they are used to do things and are forms of actions. In addition, they allow an attentive reader to get a sense of how a society or community understands itself.[481] Their reflexivity is not confined to commentary on social institutions but they are set up to be interpreted. Texts offer unique insight into their own operations as acts of cultural instauration, and are capable of revealing something about the inner processes of instauration.[482]

The documents of the NAS, CIRM, ISSCR, AMS, DCE and the EU Chimbrids project each retain their own distinct character and form, but their 'focal points' are 'social technologies' that enable re-imagining and the generation of other social facts.[483] The social facts that this and other documents carried were informational resources for the BAC and its Secretariat in the construction of the consultation papers. Collectively, these documents could constitute 'global scripts', but this may be too much of a generalization. Each document and the reflexivity entailed must be learnt and any form that is subsequently developed in the BAC's documents is unique to the local context. Of course, this script could be generalized but usually at some cost to its practicability. Each 'focal point' could open up into a distinct cognitive space, but this need not necessarily be 'global'.

Another important contribution of globalization, as Peer Fiss and Paul Hirsch observe, is that it is also a process by which the meaning of events is socially constructed and negotiated.[484] Within

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481 Karin Barber. *The Anthropology of Texts, Persons and Publics: Oral and written culture in Africa and beyond.* Cambridge: Cambridge University Press, 2007, at 4.

482 *Ibid*, at 5.

483 Stephen J. Collier and Aihwa Ong. Global Assemblages and Anthropological Problems. In Aihwa Ong and Stephen J. Collier, *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems.* Singapore: Blackwell Publishing, 2005, pp. 3-21, at 7.

484 Peer C Fiss and Paul M Hirsch. The Discourse of Globalization: Framing and Sensemaking of an Emerging Concept, *American Sociological Review* (2005) 70, 1: 29-52.

the frames of meaning that constitute interpretive spaces, sensemaking is enabled.[485] In the chapter that follows, we consider the practice of comparative law and comparison more generally as means of framing, sensemaking and interpretation in a policy environment. Comparison is no less a technique and technology of relationality, quite often non-volitional, and ubiquitous in a policy environment.

[485] Sensemaking is distinguished from framing in its emphasis on "the internal, self-conscious process of developing a coherent account of what is going on, while framing emphasizes the external, strategic process of creating specific meaning in line with political interests…If framing focuses on *whose* meanings win out in symbolic contests, sensemaking shifts the focus to understanding *why* such frame contests come into being in the first place, as well as how they are connected to "hard" structural changes, and over which territory they are fought". *Ibid*, at 31 (emphasis in original).

CHAPTER 4

COMPARATIVE LAW AS TECHNOCRATIC PRACTICE AND SELF-KNOWLEDGE

Abstract

Comparison in the form of comparative tables is ubiquitous in bioethics and taken for granted. Legal and non-legal norms are regarded as effectively similar, thereby lending support to the argument of Hans Kelsen that differences are mainly attributable to a variety of analytical or prescriptive standpoints. To a large degree, this phenomenon could be seen as a result of theoretical syllogism supported by pre-existing normative discourses and frameworks. On a level normative platform, comparison becomes functional in terms of relating problem to goal, and incommensurability is overcome. In this chapter, it is argued that comparison is not merely functional, but also relational and reflexive. Comparison creates normative positionality, which arises from the making of associative claims. This exercise is closely related to reputational standards (eg perceptions of 'good medical practice') and has often been strategically deployed to advance certain policy agenda. However, positionality contributes to reflexivity, so that the ordering and internalization entailed in comparison is also interpretive sense-making, which could make a profound impact on the comparatist 'self'. In particular, comparison could instill a sense of solidarity. This in turn confers a degree of durability on the relations drawn, and blurs the distinction between technique and epistemology in comparison.

4.1 Introduction

Annelise Riles provides an intriguing account of Henry Wigmore's idiosyncratic "parade of oddities" that ranges from facsimiles of the American Declaration of Independence to an eight-foot-tall copy of the stone bearing the Hammurabi Code.[486] Even more so is the parallel that she draws between Wigmore's collection with the treasure boxes of Ming and Qing emperors. Indeed the diverse array of curio stands now exhibited at the Forbidden City in Beijing were likely to have displayed fascinating artifacts from different civilizations, cultures and historical episodes collected by the Imperial household. Whether in treasure boxes or on display stands, these collections tell us some things about the time and place from which the objects were drawn, or at least their imputed meanings. For Henry Wigmore and perhaps for the emperors of late Imperial China, the experiences that these collections invoke are arguably similar to what one would gain from a reflective visit to say, the British Museum. Although one can never quite fully understand the stories, beliefs, practices, mindsets or cultures surrounding the collections, they could confer on one a sense of the place that Britain has in the world. One could further imagine that in studying a French tea cup in his collection, a Qing emperor better appreciates Chinese tea culture through contrast with French upper class sensibilities in tea appreciation.[487] In other words, the objects in the emperor's collection confer a self-understanding by mapping the place of Chinese civilization in the world. This knowledge of self comes not only from the constituent artifacts in the collections, but from the collections in their entirety.

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[486] Annelise Riles, Wigmore's Treasure Box: Comparative Law in the Era of Information. *Harvard International Law Journal* (1999) 40, 1 : 221-283, at 258.

[487] *Ibid*, at 268 and 277.

The office of the BAC Secretariat is relatively modest in size when compared with the offices of similar bodies such as the Danish Council of Ethics. However, not far from the main door and just outside the meeting room is an in-built cabinet that stretches from ceiling to floor and across the entire West wall. Behind the sliding doors that conceal the cabinet shelves are rows of neatly aligned folders, marked and segregated by country. Within each folder are documents on bioethical laws, regulations and policies of the country labeled on the folder. Placed alongside these folders are publications of different bioethical bodies, similarly segregated by jurisdiction. At certain parts along the shelves, one would find souvenir-like objects, either from visitors to the Secretariat or from visits overseas. This impressive display is not unlike museum collections or collections of the Ming and Qing emperors. But unlike the artifacts of the Imperial household, many of the folders and publications constitute the Secretariat's tools of trade. These materials both enable and arise from comparative work that the Secretariat actively engaged in. In fact, it is difficult to think about policy work without some form of comparison being undertaken. In the course of preparing materials and documents for consideration at meetings of the BAC and its Working Group, as well as for meetings with their consultation parties, one of my key responsibilities with the Secretariat was to determine comparatively how other jurisdictions were addressing similar bioethical concerns. There appeared to be a common mindset among policy-makers, scientists and interested members of the public alike that there was not only a shared understanding of these concerns, but also some common response to them. Hence a genuine interest in relevant international responses and developments was evident in all quarters. More importantly, these bioethical concerns were both understood and responded to relationally, and in some instances, collaboratively.

This chapter considers the way in which comparative projects of the BAC in relation to its report on human oocyte donation and research involving human-animal combination have been carried out. In particular, I attempt to explicate the comparative mentality, comparative law-as-technocratic practice, and their epistemological and relational significance. Although policy work is a critical state function, it operates beyond the nation-state as policy workers have to "reach 'upwards' to the international level, 'sideways' to business groups and non-governmental organizations, and 'downwards' to local communities and social groups."[488] This aspect of policy work is perhaps most evident in the comparisons that appears to me to be near ubiquitous in the policy environment. As we shall see, comparisons undertaken by the BAC cuts across all these domains. At the international level, many transnational documents and organizations continue to exert significant influence over how 'ethical' conduct should be understood and practiced. There is indeed significant effort, spearheaded by international organizations such as UNESCO and WHO, to harmonize and operationalize certain standards pertaining to biomedical research. In recent years, this agenda has taken an increasingly institutional form around the globe. As a policy body, the 'upwards' reach of the BAC has always been influenced by interests 'sideways' and 'downwards'. Comparison creates relationality that is both discursive (at the level of narratives) and political (among jurisdictions, commonly referred to as 'benchmarking'). Annelise Riles has illustrated a way in which such relationality could provide a justification for change.[489] In the comparative projects of the BAC, any such change that comparative relationality invokes would not find sufficient legitimacy unless also supported at some level by

[488] Hal Colebatch, Robert Hoppe and Mirka Noordegraaf, Understanding Policy Work. In Hal K Colebatch, Robert Hoppe and Mirko Noordegraaf (eds), *Working for Policy*. Amsterdam: Amsterdam University Press, 2010, pp 11-25, at 21-22.

[489] In her study, Annelise Riles observes that comparative argument presented in graphical form to show a lack of 'global standards' is commonly used in many documents of the Japanese government to advance law reform projects. As we shall see, such comparative argument is also commonly utilized in the policy environment of Singapore. Annelise Riles, *Collateral Knowledge: Legal Reason in the Global Financial Market*. Chicago: University of Chicago Press, 2011, at 206-207.

interests ‘sideways’ and ‘downwards’. This is due in part to the discursive emphasis in bioethics on giving due regard to ‘local’ conditions. In considering comparative law-as-technocratic practice and mindset, the ‘upward’ reach has a normative character and procedural form, as the sections that follow will make clear.

4.2 Oocyte Donation – Enabling Comparison at the Level of Norms

The proto-consultation paper entitled ‘Human-Animal Tissue Combinations and the Donation of Eggs for Biomedical Research’ was the main subject of discussion when the BAC met in August 2007. Women were delineated as a particular group of research subjects by the oocytes that could only be obtained from them. Being consistent with a general perception of biological ‘truth’, this delineation was not a difficult one to make, unlike human-animal combinations also addressed in the paper. Whereas the delineation between men and women on the basis of oocyte production reinforced a categorical (and biological) conceptualization of ‘women’, human-animal combinations were regarded as fudging the delineation between human beings and non-human animals (especially primates). Hence the decision to split the draft into two consultation papers arose in part from the recognition that egg donation would not give rise to subject matter complications in a way that human-animal combinations were expected to. This assessment turned out to be correct in that the subsequent categorical definition of ‘women’ in both the ED consultation paper and ED report did not attract any opposition or serious contention, not even from women-interest groups that have voiced concerns over reductionist conceptualization of women’s roles and rights in society. Another reason for the ready acceptance of this delineation

could be circumstantial. The scandal revolving around Professor Hwang Woo-Suk brought public attention to the very real risk that women could be exploited for research. Hence the introduction of measures to safeguard the interests of women in stem cell research – and any delineation to that effect – was a welcomed development.[490] The delineation and constitution of 'women' as a special class of research subjects will be discussed later on in the dissertation. Here, we consider the contribution of comparative law as technocratic tool to the problematization and comprehension of oocyte donation in stem cell research, as well as of human-animal combination, and their resolution.

The 'problematization' of women as potential donors of oocytes for research entailed a reasoning process that seems to me quite like conventional legal analysis, in that it encompassed thinking through a series of questions. We first asked whether oocyte donation should be allowed at all. If this was to be prohibited, it would be necessary to consider alternatives in view of the fact that oocytes are required to advance stem cell science and technology. However, if oocyte donation was to be allowed, public concerns over possible ethical infractions similar to those witnessed in South Korea would have to be addressed. As with the BAC's previous projects, research was undertaken by the Secretariat to determine, through comparison, the policy and regulatory responses of common law and leading scientific jurisdictions.

Only a limited number of jurisdictions have specifically considered oocyte donation for the purposes of stem cell research. And even for these jurisdictions, the central concern has been with human fertility and artificial reproduction. Furthermore, there was significant divergence in

[490] Interestingly, even a number of key organizations concerned with women's welfare did not think they have any significant role to play in the public consultation. Fieldnotes, 7 November 2007.

regulatory responses to the procurement, use and disposal of oocytes, as well as the treatment of women. This could be an outcome of what the authors of the 2007 Surveillance report of the IFFS consider to be a struggle between the requirements of good medical practice and societal values (such as human dignity) on human procreation.[491] Although primarily concerned with ART, the 2007 Surveillance was an important document to the BAC for at least four reasons. First, it was a source of information on "why and what society is trying to achieve by its monitoring of ART".[492] More importantly for the Secretariat, this information also related to the legal or regulatory constructions of oocytes and embryos. Second, it offered valuable insights on how the medical profession viewed, and contributed to, these constructions. Third, there was breadth of coverage and a policy orientation that rendered the information more accessible and useful, even though it was not otherwise detailed or adequately referenced to the respective sources. Fourth, the tabular analysis of comparative information in relation to countries with statutes or laws on ART and on donation of gametes provided inspiration to the BAC on the type of analysis it could deploy for its own report. Indeed, the comparative tables set out in the BAC's ED Consultation Paper and ED Report[493] on regulatory approaches to egg donation are broadly similar to the tabular analysis of the IFFS on donation of gametes.[494]

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491 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07. *Fertility and Sterility* 87 Suppl 1: S1-S67. The struggle between 'good medical practice' and societal values has been explicitly set out in the Federation's 2010 Surveillance: "The great variations in the details of what can and cannot be done under legislation and guidelines from country to country suggest that influences are at work other than the goal of good medical practice." See Howard Jones Jr., Ian Cooke, Roger Kempers, Peter Brinsden and Doug Saunders (eds), *IFFS Surveillance 2010*. Mount Royal, NJ: International Federation of Fertility Societies, September 2010, at 11.

492 2007 Surveillance: *Ibid* at S5.

493 Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, 7 November 2008, at 18-19, and at A-19-A-20.

494 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07. *Fertility and Sterility* 87 Suppl 1: S1-S67, at S29-S30.

Apart from the IFFS 2007 Surveillance, a report by the European Commission on reproductive cell donation (EC RCD Report) was similarly helpful.[495] This comparative project was undertaken to determine the extent to which European Union member states have implemented the Directive on human tissues and cells,[496] and to address concerns over reports that some Romanian women have been exploited for eggs.[497] The EC RCD Report provided more substantial information and was more rigorous in its analysis than the IFFS 2007 Surveillance given the ability of the European Commission to obtain relatively detailed information from many of its 23 member states and its narrower focus on essentially four concerns pertaining to reproductive cells (being informational privacy, compensation, consent and cross-border dealings).[498] Similar to the IFFS 2007 Surveillance, the EC RCD Report sets out comparatively the four different regulatory responses that member states have adopted: (1) explicit regulation through law or government rules that are legally binding, (2) national or international guidelines that are binding, (3) national or international guidelines that are not binding, and (4) no regulation.[499] A jurisdiction-by-jurisdiction tabular presentation of the regulatory responses and sources (where available) to three of the four main concerns was also provided to substantiate the conclusions derived.[500] In contrast, the IFFS devised three categories of regulatory responses: (a) Legally binding law, regulation or guidelines, (b) guidelines that are binding although not

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495 European Commission. *Report on the Regulation of Reproductive Cell Donation in the European Union: Results of Survey*. Brussels: European Commission, February 2006.

496 European Parliament and European Council. *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*, Article 12 (on compensation).

497 European Commission. *Report on the Regulation of Reproductive Cell Donation in the European Union: Results of Survey*. Brussels: European Commission, February 2006, at 2.

498 In contrast, the 2007 IFFS Surveillance covered ART practices in 57 countries. The number of countries covered increased to 162 in the 2010 IFFS Surveillance.

499 European Commission. *Report on the Regulation of Reproductive Cell Donation in the European Union: Results of Survey*. Brussels: European Commission, February 2006, at 7-8.

500 *Ibid*, at 10-17.

necessarily of a legal or regulatory nature, and (c) no regulation.[501] Under this scheme, a country would be (in relation to donation of gametes for instance) "covered by statute", "covered by guidelines" or "Not covered by statute or guidelines".

Given the breadth of the 2007 IFFS Surveillance, the authors indicated that their classificatory scheme was devised to provide a very general overview of the regulatory landscape for ART and to facilitate discussion. They recognized that "the classification is admittedly arbitrary in that some part of an ART program may be subject to national legislation, whereas other parts and perhaps the major part are covered by guidelines".[502] Although the simplicity in approach presented a very general level of commonality, subtle distinctions have not been properly accounted for. A negative implication of this could be a greater risk of misunderstanding or that the classification might itself be rendered inaccurate. For instance, the classification of Singapore as a 'guidelines' country in the 2007 IFFS Surveillance is itself problematic.[503] While the reference source was not explicitly indicated, the relevant 'guideline' would be a set of directives issued by the Ministry of Health on assisted reproduction services,[504] under which oocyte donation is permitted provided that certain requirements are observed.[505] However, as the binding authority of the directives is derived from the *Private Hospitals and Medical Clinics*

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501 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07. *Fertility and Sterility* 87 Suppl 1: S1-S67, at S9. In the 2007 Surveillance, a separate table (at S11) provided information on whether a statute-covered country has a licensing body, the manner in which clinical surveillance has been conducted and the penalty for non-compliance. In the 2010 Surveillance, both tables (on regulatory responses and licensing body) were merged into a single table: Howard Jones Jr., Ian Cooke, Roger Kempers, Peter Brinsden and Doug Saunders (eds), *IFFS Surveillance 2010*. Mount Royal, NJ: International Federation of Fertility Societies, September 2010, at 13-15.

502 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07. *Fertility and Sterility* 87 Suppl 1: S1-S67, at S8.

503 *Ibid*, at S9.

504 Ministry of Health, *Directives for Private Healthcare Institutions providing Assisted Reproduction Services: Regulation 4 of the Private Hospitals and Medical Clinics Regulations (Cap 248, Reg 1).* Singapore: Ministry of Health, 2006 (revised).

505 The IFFS has correctly indicated this in a table on donation of gametes: Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07, *Fertility and Sterility* 87 Suppl 1: S1-S67, at S30.

Act,[506] it would have been more appropriate to categorize Singapore as a 'statutes' country instead. It may be that as there is no legislation that specifically addresses ART, this linkage between the directives and its originating legislation was missed out. Also omitted in the 2007 IFFS Surveillance was the *de facto* role that the Ministry performed as the licensing body of ART clinics under the same legislative framework.[507] In comparison to the UK for instance, Singapore could be interpreted as a 'guidelines' country as it does not have a specific legislation on ART and a specific licensing body (whereas the UK did in the form of the Human Fertilization and Embryology Authority). Relative to the US however, Singapore should properly qualify as a 'statutes' country as it has a regulatory framework that is constituted under legislation and operates on a licensing system. Interestingly, the IFFS revised its categorization in 2010, listing Singapore as a 'statutes' country *with* a licensing body,[508] when there have been no major change to the regulatory framework from 2007. Curious enough, Singapore remains categorized as a 'guidelines' country in the tabular analysis of donation of gametes.[509]

A challenge in comparative analysis is the de-contextualization and generalization that are entailed. Continuing with our analysis of Singapore, legislation is usually intended to create a general framework within which more substantive provisions are set out in regulation (under a variety of names such as directives, rules or guidelines). This is especially true of those that are directed at technological matters (including biomedical sciences), as the law is often viewed as

506 Singapore Statutes: Chapter 248, amended 2008.

507 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07. *Fertility and Sterility* 87 Suppl 1: S1-S67, at S11-S12.

508 Howard Jones Jr., Ian Cooke, Roger Kempers, Peter Brinsden and Doug Saunders (eds), *IFFS Surveillance 2010*. Mount Royal, NJ: International Federation of Fertility Societies, September 2010, at 15.

509 *Ibid*, at 50.

slow to change and hence lagging behind.[510] There are exceptional statutory responses that arise from time to time, such as the *Human Cloning and Other Prohibited Practices Act,*[511] but even then, it is not prescriptive as to procedural details and it was enacted under relatively unusual circumstances.[512] The very process of de-contextualization and generalization began from the initial stages of the research in the attempt to understand and concisely describe the regulatory positions of different jurisdictions on the subject of oocyte donation and the salient concerns that they addressed. As the authors of the 2007 IFFS Surveillance observed, a number of countries made this task a formidable one.[513] Among the 'core' common law jurisdictions, Australia, India and the United States were such countries. All three jurisdictions did not have any national legislation that addressed ART, but have relied on a less direct form of control. In India, ART clinics are accredited by state-level accrediting authorities. A state authority is 'regulatory' in that it could order the closure of a clinic within its jurisdiction or levy fines. The guidelines that the state regulatory authorities implement are prescribed by the Indian Ministry of Health and Family Welfare, and are hence 'national' standards.[514] The exact legal status of the guidelines is unclear but as they are issued by the central government, state regulatory authorities would be expected to implement them, particularly since India is a unitary state. For federalist jurisdictions

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510 Interview with Associate Prof Terry Kaan, 16 June 2009. The reasons underlying this view are varied and complex. On the one hand, statutory laws are regarded by some policymakers as embodiment of social consensus or values. Consequently, laws are not to be readily adopted, revised or repealed. Others consider any changes to or repeal of laws to undermine their institutional credibility. Still others, particularly the bureaucracy, adopt this view in order to keep laws general and so secure for themselves maximum operational flexibility. This view is further discussed in a later chapter.

511 Singapore Statutes: Chapter 131B, 2005 Revised Edition.

512 I have considered the unique circumstances leading up to its enactment elsewhere. See WL Calvin Ho, Governing Cloning: United Nations' Debates and the Institutional Context of Standards. In B Capps and A Campbell (eds), *Contested Cells: Global Perspectives on the Stem Cell Debate*. London: Imperial College Press, 2010, pp 121-154.

513 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), IFFS Surveillance 07. *Fertility and Sterility* 87 Suppl 1: S1-S67, at S8.

514 Government of India (Ministry of Health and Family Welfare) and National Academy of Medical Sciences (Indian Council of Medical Research), National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India. New Delhi: S. Narayan & Sons, 2005.

of Australia and the United States, ART clinics fall within the almost exclusive purview of their constitutive states. In Australia, ART practices in the state of Victoria are strictly regulated by state legislation.[515] While the situation is similar in the United States, the federal government exerts some degree of control over ART research through the Food and Drug Administration (FDA). For instance, embryology laboratories and implantation of gametes (falling within the definition of tissue transplantation) must meet regulatory requirements of the FDA.[516]

Unlike the IFFS Surveillances, no caveat or indication of categorical ambiguities has been reported in the EC RCD Report. Greater confidence on the part of the EC in categorization of regulatory approaches or responses may be attributable to its narrower issue focus and reliance on the Directive as an interpretive framework. A helpful aspect of the EC RCD Report was its brief descriptions of regulatory positions (including sources), as supplementary information to the comparative analysis. This issue-specific country-by-country analysis was adopted by the BAC Secretariat in conducting its background work. Information produced was presented within an interpretive framework developed based on key 'markers' or considerations derived from ethical, legal and regulatory literature. With growing interest in stem cell technology and the scandal around Professor Hwang, there was a sizeable literature on the subject. These key 'markers' were drawn from regulatory provisions relating to oocyte donation for non-treatment purposes, consent requirements, payment and unexpected occurrences from the donation. Once

515 The relevant state statutes are *Assisted Reproductive Treatment Act 2008*, *Research Involving Human Embryos Act 2008* and *Prohibition of Human Cloning for Reproduction Act 2008*.

516 Under the US Code of Federal Regulations (CFR) 21 Part 1271 on Human Cells, Tissues, and Cellular and Tissue-based Products, facilities that perform IVF treatments are required to register with the FDA.

substantiated, this interpretive framework was re-formulated as an overview of regulatory positions pertaining to oocyte donation for research. Table 4 is a segment of this overview.[517]

Table 4. Regulatory Landscape in Select Jurisdictions on Egg Donation

Country / Organisation	Women not undergoing fertility treatment as oocyte donors for research	Consent Requirements	Payment / Compensation / Reimbursement	When unexpected event occurs	Comments / other requirements
China Ministry of Health and Ministry of Science and Technology Guidelines	Not specified	Written informed consent required	Selling or/and buying of human gamete, zygote or embryo prohibited	Information not available	Privacy of donor protected; IRB responsible for approval and supervision of the research.
India Indian Council of Medical Research (ICMR) Department of Biotechnology, Ministry of Science and Technology (DBT)	Allowed (Para. 11.4)	Informed consent required Minimum information provided in the Guidelines The attending physician responsible for the infertility treatment and the investigator deriving or proposing to use hES cells preferably should not be the same person.	No commodification of human egg, sperm or embryo or somatic cells for use in SCNT, by way of payment or services, except for reimbursement of reasonable expenses incurred by the person {amount to be decided by the Institutional Committee for Stem Cell Research and Therapy (IC-SCR) / National Apex Committee for Stem Cell Research}.	Research subjects who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, their dependents are entitled to material compensation (ICMR, Ethical Guidelines for Biomedical Research on Human Subjects, 2000 (p 21, Section V).)	IRB and IC – SCRT to review and approve the process of procurement of gametes, blastocysts or somatic cells for the purpose of generating new hES cell lines, including procurement of blastocyts in excess of clinical need from infertility clinics.

[517] Fieldnotes, 20 August 2007.

Table 4 (Continued)

Country / Organisation	Women not undergoing fertility treatment as oocyte donors for research	Consent Requirements	Payment / Compensation / Reimbursement	When unexpected event occurs	Comments / other requirements
Singapore Guidelines for Private Healthcare Institutions providing Assisted Reproduction Services: Regulation 4 of the Private Hospitals and Clinics Regulations (Cap 248, Rg 1) NMEC, Ethical Guidelines on Research involving Human Subjects	Allowed (AR Directives 8.6)	Explicit consent required Comprehensive information to be provided When consent is taken, there should be no coercion, inducement or undue influence. The principal physician and embryologist in charge of the patient's AR treatment must not be the principal investigator of the research team working on the same oocyte and/or resulting embryo obtained from his/her patient.	Commerce and sale of donated materials prohibited.	In the event of any significant injury, the subject must be entitled to receive compensation regardless of whether there may or may not have been legal negligence or legal liability on any other basis. Where no provision for compensation has been made, this fact ought to be disclosed to the research subjects before the initiation of the study. (NMEC Ethical Guidelines on Research involving Human Subjects, Section 3.3.2)	IRB and MOH approval required for all research involving human embryos and oocytes. Clinic performing the oocyte retrieval must be licensed by the MOH. Potential oocyte donors, who are not undergoing any fertility treatment, must be interviewed by a panel. The panel must be satisfied that the prospective donor is of sound mind, has clear understanding of the nature and consequences of the donation and has given explicit consent without coercion or inducements.

Table 4 (Continued)

Country / Organisation	Women not undergoing fertility treatment as oocyte donors for research	Consent Requirements	Payment / Compensation / Reimbursement	When unexpected event occurs	Comments / other requirements
UK HFE Act, 1990 HFEA Code of Practice, 6th Edition, 2003	Not allowed [HFEA Code of Practice – section 5.8 (ii)] Currently the sources of human eggs for research are eggs that failed-to-fertilise during IVF cycles or eggs donated from women undergoing sterilisation. In May 2006, the HFEA announced that it will be preparing a consultation programme on egg donation for research. This is to address the range of strong and contrasting views among professionals on this issues as well as international concern.	Voluntary - No pressure or undue influence and sufficient time allowed for decision to be made Written consent required beforehand for any observers' presence during examination, treatment or counselling Donors may specify the conditions for the use of their oocytes Withdrawal of consent allowed up till the time the oocyte is used Consent for oocyte donation to be taken: • After counseling and sufficient and appropriate information (oral + written) provided • In advance i.e. before the fertility treatment starts Where genetic research is to be carried out on identifiable samples, explicit consent must be obtained after sufficient information is provided.	From 1 April 2006, donors may be reimbursed for reasonable expenses incurred within the UK in connection with the donation and be compensated for loss of earnings (but not for other costs or inconveniences) in connection with the donation, up to a daily maximum of £55.19 but with an overall limit of £250 for each course of sperm donation or each cycle of egg donation. There is no restriction on the value of other benefits but these are limited to treatment services in the course of the donation cycle unless there is a medical reason why they cannot be provided at that time (i.e. centres are no longer permitted to offer sterilisation as a benefit in kind).	"Reasonable expenses incurred by an egg donor who becomes ill as a direct result of donating, may also be reimbursed by the treatment centre" (HFEA COP 4.3)	The objective of the research should satisfy one or more of the purposes listed in the HFE (Research Purposes) Regulations 2001 Person responsible for the infertility treatment and the research should not be the same person. Suppliers of gametes or embryos who are not individual donors may be given and may receive money or other benefits for that supply subject to the conditions. The most that they may be given or receive is enough money or money's worth to reimburse reasonable expenses. The supplier may take into account all costs, including out-of-pocket expenses connected directly with the particular supply.

To facilitate discussions in meetings, this tabular display was re-formulated to focus on critical issues that require specific attention, such as payment for oocyte donation. The table below is an excerpt from a more comprehensive table that was circulated to BAC members for discussion at a meeting:[518]

Table 5. Re-formulated Comparative Table with Focus on Payment

Country/Organisation	Donation of Human Oocytes for Research	Compensation / Reimbursement
China (Hong Kong) Human Reproductive Technology Ordinance	Oocytes may not be donated to create embryos for the purpose of research. (Section 15, (1))	No payment may be made or received for the supply of, or for an offer to supply, oocytes. (Section 16, (1))
China Ethical Guiding Principles on Human Embryonic Stem Cell Research (2003)	Oocytes may be voluntarily donated.	The buying and selling of oocytes is prohibited.
India Indian Council of Medical Research - National Guidelines For Stem Cell Research and Therapy (2006)	The donation of oocytes for research, including donations from healthy women not undergoing treatment, is permitted. (Paragraph 11.4)	Commodification of oocytes by way of payment or services is prohibited, except for reimbursement of reasonable expenses incurred by the person. (Paragraph 11.3)
Japan The Guidelines for Derivation and Utilization of Human Embryonic Stem Cells (2001)	Oocytes may not be donated to create embryos for the derivation of embryonic stem cell lines. (Article 6)	
Singapore Directives for Private Healthcare Institutions Providing Assisted Reproduction Services, Revised Mar 2006 (AR Directives) Human Cloning and Other Prohibited Practices Act 2004 (Human Cloning Act)	The donation of oocytes for research, including donations from healthy women not undergoing treatment, is permitted. (AR Directives, Paragraph 8.5)	The commercial trading in oocytes is prohibited, but the reimbursement of any reasonable expenses incurred by a person in relation to the supply of oocytes is permitted. (Human Cloning Act, Section 13) The buying and selling of oocytes shall not be carried out in any AR Centre. (AR Directives, Paragraph 4.11.2i)

[518] Fieldnotes, 21 August 2007.

Table 5 (Continued)

Country/Organisation	Donation of Human Oocytes for Research	Compensation / Reimbursement
UK HFEA Statement on Donating Eggs for research, 21 February 2007 (HFEA Statement) Directions Given under the HFE Act 1990, Giving and receiving money or other benefits in respect of any supply of gametes or embryos, Ref. D.2006/1 (HFE Directions 2006/1)	The donation of oocytes for research, including donations from healthy women not undergoing treatment, is permitted. (HFEA Statement)	A donor may be reimbursed reasonable expenses which he or she has incurred, in connection with the donation. Donors may be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum of £55.19 but with an overall limit of £250 (or the equivalent in local currency) for each course of sperm donation or each cycle of egg donation. There is no restriction on the value of other benefits which may be given to the donor, but the only benefits which may be offered for this purpose are treatment services. These services should be provided to the donor in the course of the donation cycle unless there is a medical reason why they cannot be provided at that time. (HFEA Directions 2006/1)

An improvisation that was devised to circumvent the difficulty of categorizing countries such as the US was to raise the analysis to a normative level. This came about when my colleagues at the Secretariat were confused by my initial insistence in clearly distinguishing the ethical standards of national organizations from standards prescribed by regulation or statute. For instance, the ethical recommendations of the NAS would not formally amount to the 'national' position of the US as they do not have any formal legal or regulatory effect. I came to understand, from my colleagues first and then from meetings with key stakeholders, that the formal distinction between law and non-law prescriptions was not important as the practical consequences of violation were considered to be equally punitive. It was at this stratospheric level of norms that

the recommendations (including proposed best practices and guidelines) of key national organizations (and, in the case of the US, key states such as California also) were taken to represent the 'national' position of a jurisdiction, particularly in the absence of a clear regulatory or statutory stance. This is arguably neo-positivist in orientation, as it is justified on the basis that the biomedical research and medical communities do not draw a clear distinction between law and ethics in practice, and they regard legal and ethical standards to be equally binding.[519] Within this expanded interpretive framework, the position of the US on payment for oocyte donation was presented as:[520]

[519] My fieldwork data suggests that many doctors and researchers, even some policy-makers and regulators, have this broad normative mindset towards ethical and legal requirements. This aspect of my research and its implications are further discussed below.

[520] Fieldnotes, 21 August 2007.

Table 6. Payment for Egg Donation in the US

Country/Organisation	Donation of Human Oocytes for Research	Compensation/Reimbursement
USA The Medical and Ethical Standards Regulations of the CIRM	Donation is allowed but informed consent required. The physician attending to any donor and the Principal Investigator shall not be the same person unless exceptional circumstances exist and with IRB approval.	Donors should receive no payment beyond reimbursement for permissible expenses. § 100100. Informed Consent Requirements, (b) (3) (D) (vii)
The Ethics Committee of the American Society for Reproductive Medicine - Financial Compensation of Oocyte Donors, Fertility and Sterility, E-pub 18 April 2007	Donation is allowed but informed consent must be taken before the collection of oocytes. Physicians should secure consent with a witness present and then place the consent form in a confidential file.	Compensation should be structured to acknowledge the time, inconvenience, and discomfort associated with screening, ovarian stimulation and oocyte retrieval. Compensation should not vary according to the planned use of the oocytes, the number or quality of oocytes retrieved, the number or outcome of prior donation cycles, or the donor's ethnic or other personal characteristics Total payments to donors in excess of $5000 require justification and sums above $10000 are not appropriate.
National Research Council and the Institute of Medicine of The National Academies - Guidelines for Human Embryonic Stem Cell Research, 2005, Amended 2007	Donation is allowed provided that written informed consent has been obtained. Minimum information to be provided before consent could be given. In addition, confirmation of consent required before research use and donors have right to withdraw consent before use.	Oocyte donors may be reimbursed only for direct expenses incurred as a result of the procedure, as determined by an Institutional Review Board. No cash or in kind payments should be provided for donating oocytes for research purposes. (Recommendation 16)
Bedford Stem Cell Research Foundation Guidelines for Research with Human Eggs and Egg Donor Time Commitment	Donation is allowed provided that consent is voluntary and informed.	Compensation provided for effort, travel and childcare expenses. Donor reimbursement ranged from US$560 to US$4004, depending on expenses incurred and the stage of completion.

The inspiration to analyze law in terms of its normative content could be traced to the jurisprudence of Hans Kelsen. In Kelsen's view, law is a normative system which operates on

the basis of normative imputation.[521] It is within this 'personifying fiction' that the notion of 'state' and 'person', among others, serve as a unifying point of imputation of norms.[522] More important for our analysis is his view that there is no specific system of norms that is distinctively or exclusively 'legal'. For Kelsen, differences between norms in law and those of other normative systems such as religion and ethics arise from differences in analytical or prescriptive standpoints.[523] Whereas Natural Lawyers have attempted to anchor substantive normative content in Reason (or, for some ethicists, in some rational process), he considered basic norms to be relative (as they arise from different points of view), contingent and dependent on social practice.[524] A legal system, or indeed any system of norms, must be adhered to and put into action in order for it to be regarded as valid.[525] In other words, a basic norm could only be considered to be valid only if it is "efficacious".[526] This is in turn dependent on certain social facts that constitute the content of the basic norm. Such 'social facts' are arguably similar to what HLA Hart regards as 'Rules of Recognition'.[527]

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521 Hans Kelsen (translated by Michael Hartney), *General Theory of Norms*. Oxford: Clarendon Press, 1991, at 24.

522 Jochen von Bernstorff and Thomas Dunlap, *The Public International Law Theory of Hans Kelsen: Believing in Universal Law*. Cambridge: Cambridge University Press, 2010, at 51.

523 This does not mean that legal norms and moral norms are one and the same. Kelsen points out that in law, there is an essential connection between the norm commanding certain actions and the sanction-decreeing norm in most circumstances, whereas in morality, the latter is secondary to the former in all circumstances. Hans Kelsen (translated by Michael Hartney), *General Theory of Norms*. Oxford: Clarendon Press, 1991, at 143.

524 See Andrei Marmor, The Pure Theory of Law. *Stanford Encyclopedia of Philosophy*, revised July 7, 2010, Parts 2 and 3 (available at http://plato.stanford.edu/entries/lawphil-theory/).

525 Hans Kelsen (translated by Michael Hartney), *General Theory of Norms*. Oxford: Clarendon Press, 1991, at 28. Kelsen argues that the validity of a norm is its existence: "That a norm 'is valid' means that it exists."

526 Hans Kelsen (translated by Anders Wedberg), *General Theory of Law and State*. Cambridge MA: Harvard University Press, 1945, at 29. Hans Kelsen makes this observation on the outcome of normative imputation: "There is no such thing as responsibility in natural reality. Responsibility is constituted by a normative order such as morality or law…This concept has not the negative meaning that the human will is not causally determined, but the positive meaning that human will, and consequently the human behavior caused by this will, is the end point of a normative imputation." See Hans Kelsen, *What is Justice? Justice, Law and Politics in the Mirror of Science*. Berkeley, Los Angeles and London: University of California Press, 1971, at 345.

527 H.L.A. Hart, *The Concept of Law*. Oxford: Clarendon, 1961, at 105.

While the validation of norms may be dependent on their social subscription, Kelsen follows David Hume in rejecting the viability of a linkage between the descriptive ('is') and the normative ('ought'). Indeed, his 'Pure Theory of Law' proposes law as an entirely normative construct, premised upon a hypothetical foundational norm that is both descriptive and prescriptive, and from which all other normative statements could be derived.[528] This is the famous basic norm (or *Grundnorm*), which – for Kelsen – is the only means by which objective validity of all resulting norms could be established through theoretical syllogism.[529] A critical take-away point of this jurisprudence is that norms constitute a scheme of interpretation.[530] By Kelsen's analysis, legal norms are similar to (perhaps even the same as) ethical norms once the action commanding norm is dissociated from the sanction-decreeing norm.[531] It becomes possible, consequently, to place legal norms on the same analytical plane as ethical norms for the purpose of constructing an interpretive grid or framework. As noted earlier, most policy-makers, researchers and the public assume that legal norms is part of moral norms. Almost all BAC members similarly hold this view (that legal norms are generally moral), even though they recognize the possibility of immoral laws.[532] We further consider the relationship between law and ethical approaches later on in this chapter and also in this dissertation.

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528 Hans Kelsen (translated by Max Knight), *Pure Theory of Law*, Berkeley and Los Angeles: University of California Press, 1967, at 8-9.

529 Hans Kelsen (translated by Michael Hartney), *General Theory of Norms*. Oxford: Clarendon Press, 1991, at 252-254.

530 Hans Kelsen (translated by Max Knight), *Pure Theory of Law*, Berkeley and Los Angeles: University of California Press, 1967, at 3-4.

531 Kelsen points out that while law need not be moral or otherwise rely on moral justification, it can be part of morals when legal norms are consistent with moral norms: Hans Kelsen (translated by Max Knight), *Pure Theory of Law*, Berkeley and Los Angeles: University of California Press, 1967, at 62-63.

532 The past and present BAC members whom I have interviewed were asked how they considered law to be different from ethics and morality. They were generally of the view that morality relates to personal values whereas ethics is concerned with shared values. Morality and ethics differ from law in that they are not explicitly backed by the state through sanction.

While Kelsen does not quite say what the *Grundnorm* is, if one considers it to be something like 'Everyone is to observe the law, or suffer sanction for disobedience', this could be formulated for an aspect of biomedical research as 'The procurement and provision of oocytes for biomedical research are to be done ethically'. From this fundamental premise, different values and approaches could be gathered in substantiating the different meanings of 'ethically'. The comparative table was thus constructed as a normative (interpretive) framework to 'fit in' different legal and ethical positions (and the jurisdictions they represent) on oocyte donation. Normative generality further enables the inclusion of regional and international standards in the analysis. The table would now present 'national' positions on par with regional and international standards on a common subject-specific normative platform in order to enable comparison. Relating this back to Kelsen, his 'Pure Theory of Law' similarly encompasses an international dimension. In his analytical scheme, international law was conceptualized as a formalized structure that normativized not only the relationship between states as equal subjects, but also between the state and its citizens. By this structure, an international normative order could be constituted above states, so that "a norm of international law determined the spatial and temporal sphere of validity of state legal orders…[that delimit] the material validity of state legal orders [as well as]…regulate any human conduct through the instrument of the treaty".[533] Immediately apparent is the sublimation of context and circumstance in order to attain logical consistency. This de-contextualization leads to a situation where "the relationship of both the state to the citizen and of the order of international law to the state were merely normative linkages between legal subjects that were themselves nothing more than the personified entity of a derived

[533] Jochen von Bernstorff and Thomas Dunlap, *The Public International Law Theory of Hans Kelsen: Believing in Universal Law*. Cambridge: Cambridge University Press, 2010, at 94 and 118. Kelsen's intent is to construct a 'world state' or civitas maxima, which requires neutral institutions to implement and enforce a system of universal law. See Hans Kelsen (translated by Max Knight), *Pure Theory of Law*, Berkeley and Los Angeles: University of California Press, 1967, at 328-347.

complex of rights and obligations" and that "the object of legal norms was, in the final analysis, always the conduct of individuals".[534]

To be sure, contemporary approaches have tended to rely less on formalistic construction of a universal normative order. They invariably exhibit sensitivity to cultural differences and substantive justice requirements. Take for instance Richard Evanoff's bioregional perspective on 'global ethics', where significant convergence of cultural values and norms is considered to be necessary to promote ecological sustainability, achieve social justice and maximize human wellbeing.[535] In addition, his approach encompasses not only the ideological (i.e. society and self), but also the material (i.e. ecological).[536] A motivation for developing a 'global' framework arises from a recognition of the limited explanatory power of both 'possibilism' (or 'localism') and 'determinism',[537] and the need to avoid any suggestion of a 'global monoculture', arising from the concept of 'global villages' and Wallerstein's notion of 'world system'.[538] With these sensibilities in mind, the table constructed by the Secretariat included the following regional and international standards on a single analytical platform:[539]

534 von Bernstorff and Dunlap: *Ibid*, at 72.
535 Richard Evanoff, *Bioregionalism and Global Ethics: A Transnational Approach to Achieving Ecological Sustainability, Social Justice, and Human Well-being*. New York and London: Routledge, 2011, at 37.
536 Evanoff elaborates Dieter Steiner's "human ecological triangle". *Ibid*, at 34.
537 *Ibid*, at 172-173.
538 *Ibid*, at 13.
539 Fieldnotes, 21 August 2007.

Table 7. International Standards on Payment for Human Eggs

Regional / International Organisation	Donation of Human Oocytes for Research	Compensation/Reimbursement
Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Iceland, Lithuania, Moldova, Poland, Portugal, Romania, San Marino, Slovenia, Turkey Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997)	Oocytes may not be donated to create embryos for the purpose of research. (Article 18)	The human body and its parts shall not, as such, give rise to financial gain. (Article 21)
European Society of Human Reproduction and Embryology (ESHRE) ESHRE Task Force on Ethics and Law 12: Oocyte donation for non-reproductive purposes - Human Reproduction (March 2007)	Donation allowed subject to informed consent.	Oocyte donation for research should be a primarily altruistic act motivated by the wish to contribute to the advancement of science and medicine. However, oocyte donors should receive reimbursement for all direct and indirect costs of the procedure and should receive a compensation for the time lost and inconvenience suffered during the treatment. The compensation should be fair and in proportion to the amounts currently paid to research subjects. To prevent undue inducement and disproportional recruitment among vulnerable groups, illiterate and poor women should be excluded as donors.
International Federation of Gynecology and Obstetrics Ethical Guidelines on the Sale of Gametes and Embryos	Donation allowed subject to informed consent.	The donation of genetic material should be altruistic and free from commercial exploitation. Reasonable compensation for legitimate expenses is appropriate.
ISSCR Guidelines for the Conduct of Human Embryonic Stem Cell Research (21 December 2006)	Donation allowed subject to informed consent.	Where reimbursement for research participation is allowed, there must be a detailed and rigorous review to ensure that reimbursement of direct expenses or financial considerations of any kind do not constitute an undue inducement. Financial considerations of any kind should not be based on the number or quality of the oocytes themselves that are to be provided for research. There must be monitoring of recruitment practices to ensure that no vulnerable populations, for example, economically disadvantaged women, are disproportionately encouraged to participate as oocyte providers for research. (Section 11.5b)

This simple, albeit deceptively straightforward, approach was quite immediately recognized as an important means of conveying information to the public. While interested members of the public would be keen to know how any position on oocyte donation proposed for Singapore would compare with other countries, they were unlikely to be interested in intricate details and discursive subtleties. For those who might be interested in such details, primary and secondary sources relied upon in the construction of the interpretive framework have been set out in the list of reference of the ED Report. The broad interpretive framework also helped policy-makers gain a sense of where Singapore's position was in relation to other countries. Within this framework, the position of different jurisdictions could be 'fitted in'. The 'fitting in' of jurisdictions is perhaps most clearly illustrated in this early version of a tabular display:[540]

[540] Fieldnotes, 15 August 2007.

Table 8. ‘Fitted’ Table on Egg Donation

Oocyte donation is prohibited	Oocyte donation from IVF fertility patients is permitted	Oocyte donation from healthy participants is permitted	Embryos may not be created for research	Reimbursement permitted	Compensation permitted
	Australia	Australia		Australia	
	Canada	Canada		Canada	
				Czech Republic	
			Finland	Finland	Finland
			France		
			Hong Kong	Hong Kong	
			Iceland		
	India	India		India	
			Ireland		
			Italy		
Norway					
	Singapore	Singapore		Singapore	
	Sweden	Sweden			
			Switzerland		
	UK	UK		UK	UK

However, this simple table of ‘fitted’ jurisdictions was not ultimately used in either the ED Consultation Paper or the ED Report as it was felt to be informationally inadequate. Instead,

using the same interpretive framework, an informationally richer tabular display of jurisdictional positions on the issues of concern was developed. The 'constructed' nature of the tabular display entitled "Regulatory Approaches of Selected Countries to Human Egg Donation" ultimately published in the ED Report was acknowledged in a number of qualifications presented alongside.[541] Regional and international normative standards have not been included in the table in order avoid public confusion. In the public mind, international standards could be seen as universal norms that should be observed by all jurisdictions. If so, the juxtaposition of national standards with those labeled as 'international' could undermine the legitimacy of the former. Indeed, policy-makers in Singapore would generally prefer a diversity of approaches in order to justify certain 'distinct' features in regulatory stance.

For the comparative table on oocyte donation that was put together, abstraction and interpretive application to the issues under consideration from the policy standpoint of Singapore was explicitly acknowledged.[542] It was further noted that while many jurisdictions have regulatory or professional governance frameworks to ensure that ART practices are properly carried out, donation of oocytes for research might not have been specifically addressed. In the absence of explicit provision, it was assumed that "many countries that allow egg donation for assisted reproduction would generally allow a similar donation to research that is concerned with reproduction".[543] Hence what we witness here is not only a translation of different relations of governance (be they ethical, regulatory or statutory in nature) to a more generic normative

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541 Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, November 2008, at 19, table references (1) to (4).

542 The IFFS similarly acknowledges reductionism in its approach. Howard Jones Jr., Ian Cooke, Roger Kempers, Peter Brinsden and Doug Saunders (eds), *IFFS Surveillance 2010*. Mount Royal, NJ: International Federation of Fertility Societies, September 2010, at 11.

543 Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, November 2008, at 19, table reference (4).

template, but also the re-definition of essentially medical concerns (i.e. in ART) to research interests. In other words, if egg donation for assisted reproduction is allowed, the implication would be that such donation should be allowed for research directed at improving ART. However, such an implication could not be extended to oocyte donation for stem cell research, which might be regarded as morally repulsive or sensitive. Where such information was unavailable, this was duly indicated in the table as 'NI'. In addition, it was made clear that the table was not concerned with reproductive or therapeutic cloning even though oocytes would be obtained for this technological application. The ethical, legal and social implications of this technology have been considered in an earlier report.[544] Instead, the table is primarily concerned with the permissibility of oocyte donation for the purposes of research (stem cell research in particular) and with payment where such donation is permitted. The two components of payment (an issue we will discuss further later on) – being compensation and reimbursement – are reiterated. Although the table is intended to be instructive, the information presented is not a precisely accurate representation of the regulatory approaches of foreign jurisdictions. To a large extent, this is due to limitations in the construction process itself, especially with problems of interpretation and translation. The basis on which countries were selected for consideration was also explained as including "availability of information (in English), availability of legislation and guidelines (both legally binding and non-binding) on the issues considered, and the extent that these issues have been deliberated on and debated in those countries."[545] The table ultimately published in the ED Report is set out below for easy reference:[546]

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544 Bioethics Advisory Committee, *Ethical, Legal and Social Issues in Stem Cell Research, Reproductive and Therapeutic Cloning*. Singapore: Bioethics Advisory Committee, June 2002.

545 Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, November 2008, at 19, table reference (2).

546 *Ibid*, at 18-19. The footnote references have been edited out of the table in the interest of conciseness.

Table 9. Published Comparative Table on Egg Donation

Country	Egg Donation for Assisted Reproduction (AR)	Payment (Egg donation for AR)	Egg Donation for research	Payment (Egg donation for research)
Austria	✗	na	✗	na
Australia (Commonwealth)	✓	R	✓	R
Belgium	✓	C	✓	NI
Brazil	✓	NI	✓	R
Canada	✓	R	✓	R
China	✗	na	✓	R
Czech Republic	✓	R	✓	R
Denmark	✓	C	✓	NI
Estonia	✓	R	✓	R
Finland	✓	R	✓	R
France	✓	R	✓	R
Germany	✗	na	NI	NI
Greece	✓	✗	✓	✗
Hong Kong	✓	C	✓	C
Hungary	✓	C	✓	C
India	✓	C	✓	R
Israel	✓	NI	NI	NI
Italy	✗	na	NI	NI
Japan	✗	na	✓	R
Korea (South)	✓	R	✓	R
Netherlands	✓	R	✓	R
New Zealand	✓	R	✓	R
Norway	✗	na	✗	na
Singapore	✓	R	✓	R
Slovenia	✓	R	NI	NI
South Africa	✓	R	✓	R
Spain	✓	C	✓	C
Sweden	✓	R	✓	R
Switzerland	✗	Na	NI	NI
Taiwan	✓	C	NI	NI
Turkey	✗	Na	NI	NI
United Kingdom	✓	C	✓	C
USA (Federal)	✓	C	✓	C

Table 9 (Continued)

Legend:

×	Prohibited
✓	Allowed
C	Compensation allowed
R	Reimbursement of expenses allowed
na	Not applicable
NI	No information that directly addressed the issue was found or the position on the issue was unclear

In summary, diverse relations of governance vis-à-vis oocyte donation have been rendered comparable through at least two levels of generalization. By redefining regulatory and statutory relations to norms, they were rendered comparable to ethical standards. By evaluating both medical treatment and biomedical research under the broader purpose of achieving reproductive conception, two different sets of technique were rendered comparable (or at least, complementary). Through these generalizations, the comparative table ultimately constructed could be regarded as a normative epistemic framework, within which the different relations of governance on oocyte donation could be related one to another. Their positionality *inter-se* would in turn prescribe a certain value and credibility. What the comparative table obscures however is its own situatedness in the standpoint of Singapore (although, as indicated, a footnote reference admits to this).

4.3 Human-Animal Combinations – Extending the Normative Framework

A similar approach was adopted in analyzing the governance of research involving human-animal combinations. Focusing on normative content, the interpretive framework within which comparison was undertaken enabled different jurisdictions to be placed on a single scale, regardless of the different degrees of formalization. For instance, the guidelines of the NAS, where applicable to human-animal combinations, have been taken to be the 'national' position of the US for a number of reasons, including the absence of federal legislation or regulation on the subject, and its treatment as such by researchers, policy-makers and international organizations. As we have considered, the guidelines of the NAS on human-animal combinations served as a model for the regulatory framework in the state of California and for the ISSCR. In constructing a comparative table on the subject, the BAC Secretariat again acknowledged that the information presented "need not necessarily be a complete representation of the regulatory approach of the specified country" and that the selection of jurisdictions are "based on several factors including availability of information (in the English language), availability of legislation and regulatory guidelines (both legally binding and non-binding), and the extent that these issues have been deliberated on and debated in these countries".[547] In addition, for reasons discussed in the earlier chapter, the sub-categorization of human-animal hybrids as 'true hybrids' and 'cytoplasmic hybrids' in the HA Consultation Paper was subsequently reduced to a single category of 'cytoplasmic hybrid embryos'. As illustration, an excerpt showing the regulatory approaches of Japan (with regulatory provisions), Singapore (no specific provision), the UK (with statutory

[547] Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at A26. The caveat on incomplete representation was not repeated with the table published in the ED Report (at 27).

provision for cytoplasmic hybrid embryos) and the US (with comprehensive non-regulatory guidelines) from the table published in the HAC Report is set out below:[548]

[548] See full table at: Bioethics Advisory Committee, *Human-Animal Combinations in Stem Cell Research*. Singapore: Bioethics Advisory Committee, September 2010, at 27-34.

Table 10. Comparative Table on Chimeras and Cybrids

Country	Animal Chimeras	Cytoplasmic Hybrid Embryos
Japan *The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques*, 2001 *Guidelines for the Handling of a Specified Embryo*, 2001 *Guidelines for the derivation and distribution of human embryonic stem cells*, 2009 (drawn from Caulfield T *et al*, "Stem cell research policy and iPS cells", *Nature Methods*, 7(2010): 28-33) *Guidelines for the utilization of human embryonic stem cells*, 2009 (drawn from Caulfield T *et al*, "Stem cell research policy and iPS cells", *Nature Methods*, 7(2010): 28-33) Science Council of Japan, *Guidelines for Proper Conduct of Animal Experiments*, 1 June 2006	The creation of animal chimeric embryos is allowed, with approval from the Ministry of Education, Culture, Sports, Science and Technology (MEXT) is required (Article 2(1) of the 2001 Guidelines, and Article 6 of the 2001 Law). The transfer of such embryos into a human or non-human uterus is prohibited (Article 3 of the 2001 Law). Research involving the production of germ cells from pluripotent stem cells (whether from human embryonic stem cells or iPS cells) should be allowed under strict oversight, but fertilisation using these derived gametes should be prohibited. In addition, research involving the grafting of human iPS cells into animal embryos is allowed, although implantation of such embryos into an animal uterus is prohibited (2009 Guidelines). There are no specific regulations or guidelines on the creation of animal chimeric foetuses or post-natal human chimeras for research. There are guidelines on the use of animals in research.	The creation of cytoplasmic hybrid embryos is prohibited (Article 2(1) of the 2001 Guidelines, and Article 2(1)14 of the 2001 Law). (Further reference: Taupitz J and Weschka M (eds). *CHIMBRIDS – Chimeras and Hybrids in Comparative European and International Research*. Heidelberg: Springer, 2009. Page 1029.)
Singapore *Human Cloning and Other Prohibited Practices Act*, 2004 *Animal & Birds (Care and Use of Animals for Scientific Purposes) Rules*, 2004 National Advisory Committee for Laboratory Animal Research, *Guidelines on the Care and Use of Animals for Scientific Purposes*, 2004	There are no specific regulations or guidelines on the creation of animal chimeras for research. There are guidelines on the use of animals in research.	It is unclear if the creation of cytoplasmic hybrid embryos is regulated under the Act.

Table 10 (Continued)

Country	Animal Chimeras	Cytoplasmic Hybrid Embryos
United Kingdom *Human Fertilisation and Embryology Act* 2008 *Animals (Scientific Procedures) Act*, 1986	There are no specific regulations or guidelines on the creation of animal chimeras for research, apart from those that relate to the welfare of laboratory animals.	The creation of cytoplasmic hybrid embryos is allowed only if under licence from the HFEA. (Sections 1(2) and 4(2) of the Act). Development of such embryos beyond 14 days or after appearance of the primitive streak, whichever is earlier, and implantation into a woman or an animal, are prohibited (Sections 4(2)(1), 4(3) and 4(4) of the Act).
United States of America National Academy of Sciences (NAS), *Guidelines for Human Embryonic Stem Cell Research*, 2005, amended 26 May 2010 National Institutes of Health (NIH), *Guidelines for Research Using Human Stem Cells*, 2009 *Animal Welfare Act*, amended 1990 State law varies significantly, with a number of states that allow nuclear transfer research and a number that do not.	There is no provision under Federal law for the creation of animal chimeras for research, although the use of certain animals in research is regulated by law. Under the NAS Guidelines, the creation of animal chimeras for research is allowed, after additional review and approval by an Embryonic Stem Cell Research Oversight (ESCRO) committee (Paragraphs 1.3(a), 1.3(b)(ii) and 1.3(b)(iii)). Animals into which human embryonic stem cells have been introduced such that they could contribute to the germ line should not be allowed to breed (Paragraph 1.3(c)(iii), NAS Guidelines; Part IV (B), NIH Guidelines). However, the introduction of human embryonic stem cells into non-human primate embryos should not be conducted at this time (Paragraph 1.3(c)(ii), NAS Guidelines) / is ineligible for funding (Part IV (A), NIH Guidelines).	There is no provision under Federal law for the creation of cytoplasmic hybrid embryos for research. Under the NAS Guidelines, the creation of cytoplasmic hybrid embryos is allowed. Development of such embryos beyond 14 days or appearance of the primitive streak, whichever is earlier, and implantation into a human or non-human uterus are prohibited (Paragraph 4.5). When hES cell lines are to be derived from cytoplasmic hybrid embryos, the approval of an ESCRO will have to be obtained (Paragraph 4.4, NAS Guidelines).

4.4 Positional Relationality in Comparative Tables

Comparative tables bear some resembles to a *huanghuali* yoke-back chair (黃花梨官帽椅) in classical antique Chinese furniture dating back to the Ming dynasty (about 14th to 17th century). In Ming dynasty China (and indeed, much of late Imperial China), comfort and convenience in the design and construction of a chair were secondary to considerations of the hierarchy and status of its user. The location and the type of chair that a person sits on should accurately reflect her social position determined based on factors that include title, seniority and gender. At significant events, a chair may be embellished with exquisite textile and its placement must be precise.[549]

Comparative tables in a variety of forms and applications have been ubiquitous throughout the course of my fieldwork. They were common not only in the projects of the BAC, but also in the documents of different government agencies and policy bodies (local and foreign) that I dealt with. Their use and placement within documents play a critical role in determining the character and function of these documents. While comparative tables are informative in themselves, they have important symbolic significance. They communicate relationality, due diligence and hence legitimacy. I was myself responsible for the creation of some of these tables, and ultimately in their publication in the ED and HAC Reports. In the paragraphs that follow, I will first attempt to explicate my sense of what comparative tables 'do', as well as to elaborate on the ways in which epistemologically self-contained comparative tables are constructed.

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[549] Sarah Handler, *Ming Furniture: In the Light of Chinese Architecture*. Berkeley and Toronto: Ten Speed Press, 2005, at 108. More generally, certain types of chairs, such as the folding stool, were a prestigious seat and a symbol of dignity and power in ancient China, Egypt, Greece and Rome. By the late 6th century, they appeared in tombs of the wealthy. See Florence de Dampierre, *Chairs: A History*. New York: Abrams, 2006, at 37.

A key responsibility of the BAC has been set out by the Chairman as ensuring that biomedical research conducted in Singapore is ethically acceptable by international standards.[550] Operationally, the 'problem' was conceived as determining the ethical benchmark by which research goals and methods could be determined to be 'ethical'. Although there was a ready supply of ethical principles and norms, there was no immediate correlation between these principles and norms to the varied research and regulatory practices adopted by different jurisdictions. Comparison was undertaken, much in the way comparative law, to uncover what were generally perceived as 'issues' in relation to oocyte donation and human-animal combinations, and possible 'solutions' to them. This comparative approach to problem-solving entails generalization that is consistent with the observation of Annelise Riles that a purpose for undertaking comparison is the promotion of universalism at every level.[551] Apart from this problem-solving modality, other purposes that have contributed to the BAC's comparative engagements are similar to those set out by Gerhard Dannemann as (to a very limited degree) unifying law, applying foreign law, facilitating choice between legal systems, to gain understanding and enhance knowledge.[552] However, the primary motivation behind comparative work undertaken in the BAC's projects was problem-solving through understanding foreign governance approaches and to 'apply' foreign laws or regulations that are suited to 'local' goals and conditions. This is indeed one message that the BAC has sought to communicate through its comparative projects.

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550 Interview with Professor Lim Pin, 27 April 2009; Fieldnotes (correspondence 16 June 2010).

551 Annelise Riles, Introduction: The Projects of Comparison. In Annelise Riles (ed), *Re-thinking the Masters of Comparative Law*. Oxford and Portland (Oregan): Hart Publishing, 2001, pp 1-18, at 12.

552 Gerhard Dannemann, Comparative Law: Study of Similarities or Differences? In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 383-419, at 402-406.

However, this notion of comparison glosses over the constructive (and contributive) dimension of comparative work. Indeed, a legally-trained contact who was indirectly involved in the BAC's project has this to say about comparative work:[553] "Singapore is good at taking the best practices from other people. We should definitely continue to look at what leading countries are doing and then adopt those practices that are suitable for us." The assumption underlying this remark is that there are easily adaptable ethical or governance practices 'out there' that can be acquired, much like shopping for an item after price and quality comparisons are made. My experience in the field has been that there were no such ready-made standards and practices to be 'found'. Rather, the purpose behind developing a comparative table as a normative interpretive framework and determining an appropriate 'fit' is very much a concern with building positional relationality. As we have seen, comparability was achieved through the creation of a normative 'map', generated through a process of abstraction and translation of different approaches to governance of oocyte donation or human-animal combinations. It may be argued that positioning a jurisdiction at a certain location on this normative map is to also prescribe to that position a certain normative content. Sharing the mindset of early modernist comparative lawyers, these acts of mapping and attributing positions are intended to be relational.[554] The 'commonalities' that are thereby derived through generalization are primarily intended to establish normative positions.[555] Much in the way that your seating position presents your social standing in late Imperial China, positionality in comparison tables enables a claim to normative identity through drawing

553 Fieldnotes, 20 October 2010 (ShB).

554 As Riles observes: "the early modernist comparative lawyer is best understood…as a kind of independently operating bureaucrat…[the comparatists'] ideas create world – they don't just "reflect" or "influence" it. The relation between knowledge and social facts is literal, not just metaphorical". Annelise Riles, Introduction: The Projects of Comparison. In Annelise Riles (ed), *Re-thinking the Masters of Comparative Law*. Oxford and Portland (Oregan): Hart Publishing, 2001, pp 1-18, at 13.

555 Later on, Riles observes: "This bureaucratic mode of scholarship…gravitates toward particular kinds of arguments and claims. It is much better suited to demonstrating (or rather, negotiating) underlying commonalities (common cores) than to challenging or critiquing paradigms". *Ibid*, at 17.

relations with some other occupants of this locality. This claim is a normative one, and often understood as 'standards' in a policy environment. Take for instance the BAC's table on oocyte donation.[556] In allowing donation for research, Singapore is shown to share a similar position with key jurisdictions like Australia, China, Japan, the UK and the US. On the issue of payment however, the position proposed for it is mid-way between Australia, China and Japan on the one hand (where only reimbursement of expenses is allowed), and the US on the other (where relatively substantial compensation may be provided).

The current statutory position in Singapore is that there should be no payment for the donation of oocytes other than for reimbursement of certain expenses. On the grounds of fairness, the BAC has proposed for compensation to be provided to healthy donors for loss of time and earnings. However, this compensation is likely to be a limited one given the BAC's overarching concern with inducement that amounts to undue influence. Hence, while the comparative table accurately reflects the current position of Singapore on the subject of payment (in allowing reimbursement only), it does not accurately represent the BAC's proposed position. As noted earlier, the BAC was not free to choose any position it desired, as it has earlier committed to a position against all forms of commercialization of the human body. This immediately rules out the option of allowing substantial payment (as in the US) and other financial arrangements that could have this effect (such as the egg-sharing scheme in the UK). The political message from this comparative project is that while Singapore is prepared to relax its 'conservative' stance on non-payment, it is not prepared to embrace fully the 'economic liberalism' of the UK or the US. This was in fact

[556] The BAC introduces the comparative table as "a summary of the laws and guidelines of various countries on whether egg donation is allowed, and if so, whether compensation may be provided." Bioethics Advisory Committee, *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, 7 November 2007, at 17, paragraph 4.20.

the message that the Press wanted to be made explicit, and did so.[557] As we have also seen, there was a broader political agenda behind this shift in stance. A similar motivation directed the comparative work on human-animal combinations. The construction of commonalities among key jurisdictions was intended to show that human-animal combinations are not as 'novel' as people think and that there already are regulatory approaches to address some key concerns arising from the research. But as we have also seen, comparison reveals the limits of regulation and the impossibility of bridging all differences.

Another way of considering relationality is to think of comparison as a heuristic activity, and comparative tables as heuristic devices. For the BAC's work, comparative tables serve as interpretive frameworks that set out normative options for policy-makers. On the subject of oocyte donation, they could well be seen as resembling a 'scale', limited at one end by jurisdictions or organizations that preclude donation altogether, and those that allow the donation at the other end. Intermediate positions would include jurisdictions or organizations that only allow purely altruistic donations and those that allow substantial payment to be provided for the donation. This 'sliding scale' is arguably similar to those developed by Mitchel Lasser in his comparative analysis of the different degrees of formalism and transparency among the highest judicial institutions in France, the European Union and the US.[558] Lasser identifies two fundamental questions that guided the construction of his 'sliding scales':[559]

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557 For instance, the issue of payment was the focus of new reports on the release of the BAC's consultation paper on donation of oocytes for research in November 2007, followed by its recommendations in November 2008. See Chen Huifen, Payment for women's eggs being mulled. *The Business Times*, 8 November 2007; Serene Luo, Human egg donation: No payment for pain, risks. *The Straits Times*, 6 November 2008; Chen Huifen, Panel favours compensating women who donate eggs for research. *The Business Times*, 4 November 2008.

558 Mitchel des S.-O.L'E. Lasser, *Judicial Deliberations: A Comparative Analysis of Judicial Transparency and Legitimacy*. New York and Oxford: Oxford University Press, 2004, at 241-268.

559 *Ibid*, at 242.

(1) What is to be used as, and included in, the objects of comparison?

(2) With regard to what attributes are these objects to be compared?

He relies on a claim of typicality in justifying the choice of the European Court of Justice (ECJ), the Cour de cassation and the US Supreme Court for analysis and comparison.[560] This typification is both determined by and also shapes, through articulation, the discursive characters of these institutions: radical bifurcation (between the Cour and the Magistrats) in the French system, soft bifurcation (between the formal, deductive, magisterial and univocal discourse of judicial decisions in contrast to the more personal, open-ended and insecure opinion of the Advocate-General) of the ECJ, and discursive integration in the US (where facts and reasoning are all reflected in the judgment).[561] An important contribution of this constructed scale is, as Lasser explains, the revelation that while "traditional American comparative accounts have always stressed the radical formalism of French judicial decision-making, ...[he] also wanted to underline the similarly radical openness of the professional discourse of the French *haute magistrature*. The scale representation…offers a visual depiction of this characteristic French *double* radicalism".[562] When "degree of formality" is replaced with "extent of disclosure" as the scalar variable, the ECJ has been found to be more transparent whereas the Cour de cassation was the least.[563]

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560 Lasser provides this explanation: "What makes the French judicial system French, the European (EU) system European, and the American (U.S.) system American are discursive and conceptual attributes that manifest themselves throughout those judicial systems, attributes that surface again and again despite the obvious variation in the parties, the subject matter, the legal issues, and the like handled by the assorted courts in question." *Ibid*, at 297 (see also 271).

561 *Ibid*, at 256.

562 *Ibid*, at 257-258 (emphasis in original).

563 *Ibid*, at 260.

The didactic nature of comparative tables as 'sliding scales' of sorts is similarly evident in those generated by the IFFS and the BAC. In its Surveillances of 2007 and 2010, the IFFS's 'sliding scales' were the basis by which policy developments on IVF have been assessed. For instance, it considered major changes in Italy to be "retrogressive".[564] Since 2004, ART has been limited to adult heterosexual couples who are married or living together, after medical certification of sterility or infertility, and subject to a requirement that a maximum of three oocytes can be fertilized and implanted as embryos, regardless of its quality and the age of the future mother. These stringent requirements are premised on a religious belief that human 'personhood' begins at conception, which the IFFS considers to be a "cultural bias" and hence not "good medical practice".[565] It further noted that Costa Rica is a country where IVF is prohibited,[566] presumably due to a similar "cultural bias". Hence the 'scale' becomes not only a basis of assessment, but also a definition of what amounts to 'good medical practice'. The comparative tables of the BAC similarly create interpretive 'scales' that facilitate policy choices by setting out a broad spectrum of possibilities. By choosing a position within the limits of the scales, policy positions are rendered more defensible in a sense that it is not an anomaly. Certain locations on the scale might be all the more desirable if they are shared with jurisdictions of interest or influence. Hence claims to consistency with 'best international standards' are very often matters of positioning on some normative interpretive 'scale'. This is also a reason for the centrality of comparative tables in many aspects of policy work.

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564 Jean Cohen, Howard Jones Jr., Ian Cooke and Roger Kempers (eds), "IFFS Surveillance 07", *Fertility and Sterility* 87 Suppl 1: S1-S67, at S8.

565 The IFFS indicates: "The great variations in the details of what can and cannot be done under legislation and guidelines from country to country suggest that influences are at work other than the goal of good medical practice. Italy can be used as an example. Italian law limits insemination to no more than three oocytes and requires that all fertilized oocytes be transferred. This is not good 21st century medicine and reflects the cultural bias of the national legislative body." Howard Jones Jr., Ian Cooke, Roger Kempers, Peter Brinsden and Doug Saunders (eds), *IFFS Surveillance 2010*. Mount Royal, NJ: International Federation of Fertility Societies, September 2010, at 11.

566 *Ibid*.

4.5 Open-Endedness in Relational Solidarity

Although the comparative tables resemble Lasser's sliding scales, the motivations behind their construction are of a different character. Lasser's goal was to provide a more open and accommodating approach to understanding another legal system. He was critical of the restrictive approach of a generation of American comparative jurists that sought to evaluate the French legal system through an essentially American standpoint by focusing only on French appellate judgements. While judicial decisions have been central to the legal process in common law jurisdictions, they have a more limited role in the French legal system, which operated on a different master narrative directed at securing different sociopolitical goals. Lasser considers that "the comparativist must not only gather and convey detailed information about procedural structures, institutional forms, professional organizations, discursive practices, methodological approaches, conceptual frameworks, and the like; she must also decode and explain the interaction between them. This intricate work demands a good deal of ideological reconstruction: what is the dominant underlying logic and self understanding according to which, for example, the work performed by judges and other important institutional players is felt to be legitimate?"[567] In contrast to Lasser's comparative agenda, there was less immediate interest in uncovering the dominant logic embedded in master narratives of the different jurisdictions considered in the comparative work of the BAC. Instead, the focus has been on mapping out the range of policy options in relation to the issues on hand, and the means to secure legitimacy for a policy stance when one is adopted. In a policy environment, norms are not viewed in a rigid and inflexible manner but are malleable, particularly where there is a diversity of norms. Norms are

[567] Mitchel de S.-O.-l'E. Lasser, Transforming Deliberations. In Nick Huls, Maurice Adams and Jacco Bomhoff (eds), *The Legitimacy of Highest Courts' Rulings: Judicial Deliberations and Beyond*. The Hague: TMC Asser Press, 2009, pp 33-53, at 37.

thereby both resource and tool directed at achieving particular social and political agenda. To be sure, this is not to say that policy makers are disinterested in the dominant logic of the systems compared, but the desired social and political objectives tend to color the understanding and choice of jurisdictions.

The instrumental and pragmatic nature of the BAC's comparative projects appears like what Annelise Riles has observed to be the different focus (and lack of communication) between comparative lawyers and socio-legal scholars.[568] Evaluating my own frame of mind in making comparison at the Secretariat, it was not dissimilar to the comparative work that I undertook while in legal practice. In this respect, I am inclined to think of comparative work of the Secretariat as being similar in orientation to that of 'comparative lawyers'. As we have earlier considered, the BAC's approach is essentially normative and it adopts a Weberian definition of law with focus on the state and hence 'law on the books'. This orientation should not be surprising as the BAC was appointed by the state to provide it with advice, and the relevance of policy responses by other countries to similar issues is taken-for-granted. As a field, 'bioethics' tends to be construed normatively (much like Kelsen's concept of law), no less so by the BAC and policy-makers. There is also some ambivalence in the treatment of social context, as there has not been a clear or consistent rationale as to the inclusion of some social factors or considerations, but not others. On the whole, a socio-legal scholar is likely to find the legal and social analyses to be amateurish. Following Riles in her study of John Henry Wigmore's

568 Annelise Riles, Comparative Law and Socio-Legal Studies. In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 775-813, at 783-785. Elsewhere, Riles notes: "The field of comparative law is populated by three disparate groups of scholars: first, "traditional" comparative lawyers; second, specialists in particular bodies of non-Western law such as Japanese or Chinese law; and third, younger scholars working under the banner of so-called "new approaches". Annelise Riles, Wigmore's Treasure Box: Comparative Law in the Era of Information. *Harvard International Law Journal* (1999) 40, 1: 221-283, at 225.

approach to comparative law, amateurism is not intended to be a disparaging word here.[569] Riles explains that while Wigmore's comparative legal scholarship could be considered amateurism in its presentation of "a heap of raw material" composed of text that leaves glaring analytical gaps and without any attempt at analytical output,[570] she explains that these peculiarities are best understood as the influences of American (Langdellian) legal formalism, where "the text does not stand for the self in the way it does for the academic, nor does the textual debate stand for the community in which the self is constituted. This is because for the formalist, the relevant site of academic relationality is not the text but the classroom."[571] Hence the analytical gaps in Wigmore's comparative works are intended to enable contingency. While the BAC could not be said to be operating under the influence of American legal formalism, it similarly recognizes that the relevant site of relationality resides not in its reports, but in the political and bureaucratic domains. In many instances, it would not be necessary to offer so comprehensive an analysis as to dictate a definite policy trajectory. Indeed, a number of more 'targeted' recommendations of the BAC have not been 'operationalized' as they were felt to be difficult to implement or of a lower priority in the political agenda.[572] A more open-ended presentation of materials and analysis create gaps that enable flexibility in policy definition and implementation. In other words, analytical gaps in comparison make room for political and bureaucratic contingencies. To be sure, the presence of gaps should not lead to the assumption that no or inadequate analysis

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569 Annelise Riles, Encountering Amateurism: John Henry Wigmore and the Uses of American Formalism. In Annelise Riles (ed), *Re-thinking the Masters of Comparative Law*. Oxford and Portland (Oregan): Hart Publishing, 2001, pp 94-126, at 98. Indeed, Riles argues (at 125) that "…if amateurism is defined as a failure to analyze, then comparative law is inherently amateuristic", as it is this particular characteristic that sets it apart from comparative socio-legal scholarship.

570 *Ibid*, at 114. Riles adds (at 121): "The texts used in American law schools in Wigmore's time, as today, are, as their name implies, "materials" – collections of essays and documents. The idea is that the very absence of answers to the text's open-ended questions will stimulate a response from the student and spark a dynamic discussion in class; they are tools for creating a moment."

571 *Ibid*, at 122.

572 Fieldnotes, 2 August 2010 (MH).

was done. The reports of the BAC, while relatively brief, have been effective in securing legitimacy through the production of cogent arguments and through (as we have seen) positional solidarity in ethical or policy stance with leading jurisdictions. Analysis in the backroom has been very comprehensive but very little substantive materials and analytical outputs are ultimately published in the reports. This is perhaps reminiscent of the French judicial system, where decision-making procedures of the French high courts are designed to generate extensive internal judicial debates, which are not reflected in the published judicial decision.[573] Like the French judicial institution, the BAC is not composed (with the exception of one or two members in certain terms of appointment) of elected representatives. However, the brevity of its report and the relatively open-endedness of its recommendations is not so much a matter of safeguarding republicanism (as Lasser attributes to the French judicial system), than practical concerns of accessibility to policy-makers and the public alike, and of securing policy flexibility and implementability.

[573] Mitchel de S.-O.-l'E. Lasser, Transforming Deliberations. In Nick Huls, Maurice Adams and Jacco Bomhoff (eds), *The Legitimacy of Highest Courts' Rulings: Judicial Deliberations and Beyond*. The Hague: TMC Asser Press, 2009, pages 33-53, at 41.

4.6 Functionality in Normative Similitude

Let us now consider how the problem-solving mindset in making comparisons relates to the concept of 'common problem' in functionalism. Law in practice has often been viewed as essentially parochial, since the lead counsel in an international transaction will nevertheless have to rely on the opinions of local counsels to ensure the legality of the deal's local components. However, in the absence of an appropriate or clear answer to the issues on hand, Lord Bingham observes that foreign authority may be significant or decisively influential.[574] He goes further in acknowledging the importance of foreign influences,[575] especially in the resolution of shared issues in an increasingly connected world.[576]

There is a sense of *praesumptio similitudinis* in Lord Bingham's argument for the relevance of foreign laws, in that legal systems of foreign jurisdictions are considered to encounter the same problems. Even if different solutions are applied, similarly just results are desired.[577] Outside of an adjudicative setting, this presumption has been similarly applied in the BAC's comparative projects as a heuristic principle. Gerhard Dannemann suggests that while the presumption appears to find broad application in encouraging one to discover similarities in foreign laws and legal systems, it is in fact limited to those areas of substantive private law which are not culturally or politically sensitive (thereby excluding all of public law, criminal law, procedural

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574 Thomas H. Bingham, *Widening Horizons: The Influence of Comparative Law and International Law on Domestic Law*. Cambridge: Cambridge University Press, 2010, at 8.

575 Lord Bingham considers English law as "a mongrel, gaining in vigour and intelligence what it has lost in purity of pedigree." *Ibid*, at 5-6.

576 *Ibid*, at 3.

577 Konrad Zweigert and Hein Kötz, *An Introduction to Comparative Law* (trans. Tony Weir). Oxford: Clarendon Press, 1998 (Rev 3rd ed), at 40.

law and even family and inheritance law).[578] In bioethics, power over processes of life,[579] and commonality of the struggle against death and dying, are the basis of unification into a single shared problem that different civilizations have attempted to address through a variety of social institutions, including religion and law.[580] Under this rubric, different legal systems become comparable by their social function. As a key functionalist methodology, this rationale grounded in 'common problems' was among the rationales deployed by the Secretariat in the construction of its comparative tables.

In critique of this approach, Richard Hyland points out that the 'common problems' approach is only possible at a generic level. As illustration, he observes that although everyone in every society has to eat, no society or legal system has to confront food-related problems in this generic form.[581] The obscurity or fiction of generality is the result of abstraction, which is inevitable in rendering commensurability. In addition, abstraction enables functionalists to extricate law from society, so that legal norms can be applied as tools to implement social goals. However, Hyland questions the correctness of this view in his observation that "very often, the law does not work that way. The norm comes first, and only then is a particular functionality ascribed to it…If the law were functional in the way legal functionalists assume, it would demonstrate two characteristics. First, we would know the purpose for which our legal norms are

578 Gerhard Dannemann, Comparative Law: Study of Similarities or Differences? In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 383-419, at 395.

579 Marilyn Strathern points out a critical detachment from the stability of 'nature' as a given with the various interventions into life that science and technology now enable. Marilyn Strathern, *After Nature: English Kinship in the Late Twentieth Century*. Cambridge: Cambridge University Press, 1992, at 195.

580 Jack Goody, for instance, points to similarities in human cultures, common situations (structural), common development of social evolution, the logic of the situation and inherent potentialities, that enable meaningful comparisons to be made. Jack Goody, Globalization and the Domestic Group. In Max Kirsch (ed), *Inclusion and Exclusion in the Global Arena*. New York: Routledge, 2006, pp 31-41, at 33 and 36.

581 Richard Hyland, *Gifts: a study in comparative law*. New York: Oxford University Press, 2009, at 70.

promulgated. Second, we would be able to determine the social consequences of applying the norms. Yet neither characteristic describes the legal systems examined here."[582] Hyland considers that both the purpose and consequence of a norm are indeterminate, and it is impossible to find purpose in a legal norm.[583]

It is questionable if this strong Realist stance is defensible in every situation. Even if there is no inherent purpose to a legal norm and its attributed purpose is continuously reformulated, it does not mean that this purpose lack any measure of durability for a time. As earlier considered, an effect of objectification through law is meaning creation, and this has been found to be relatively durable. In addition, the work of the BAC on oocyte donation and human-animal combinations suggests that different communities have been working at different levels to secure a range of possible readings, if not a specific reading, of relevant ethical and legal norms. These communities – whether regulatory, scientific or ethical – take these norms to be the *Tertium Comparationis* by which 'common problems' could be addressed and resolved. It is more difficult to tease apart norms from problems. The work of the BAC suggests that norms did play a significant part in shaping the nature and character of both the problem and its solution(s), but there did not appear to be a perceived need to know if the norms gave rise to the problems or *vice versa* (I return to this problem-solution nexus shortly). A reason for this could be the focus on shared or common principles. Not surprisingly, debate over whether such principles may be said to be found or are matters of social construction continues. Regardless of foundational basis, principles have been an important means of initiating dialogue and achieving consensus amidst

[582] *Ibid*, at 74. Hyland describes the viewpoint of functionalists as: "They see society as a house in need of repair. We are the general contractors; the legal norms are our tools. The social problems come first. Legal norms are crafted to solve the problems."

[583] *Ibid*.

vast diversity. They have in turn provided inspiration of a universalist heritage, where different laws may in fact be based on the same principles due to differences in circumstances, values and cultures.[584] As no circumstance is ever exactly alike, James Gordley points to the centrality of principles in establishing commonality in comparative law.[585]

4.7 From Similitude to Universalism

I want to return to an earlier point relating to the normative shaping of problem and solution. Composed of individuals with different ideological and discursive backgrounds and lineages, the meeting point has often been on practical functionality of normative governance systems, including law.[586] Pre-existing bioethical discourses have been influential in advancing a sense of *praesumptio similitudinis*. For instance, universalism is apparent in the principled-basis by which Ezekiel Emanuel analyzed shifts in paradigms of medical ethics.[587] Where beneficence as determined by physicians was regarded as the dominant principle of medical ethics prior to the 1950's, he considers self-determination to be encouraged by the courts and legislatures in the 1980's. This in turn contributed to a plurality of values with no hierarchy in the medical ethics of

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584 James Gordley, The universalist heritage. In Pierre Legrand and Roderick Munday (eds), *Comparative Legal Studies: Traditions and Transitions*. Cambridge: Cambridge University Press, 2003, pp 31-45, at 40-41.

585 *Ibid*, at 44-45. Gordley seems to suggest that socio-legal comparison begins where comparative law ends.

586 Ralf Michaels considers Lasser's approach in *Judicial Deliberations* to be a functional method in that although Lasser sets out to compare judicial styles as a cultural analysis of mentalities, he explains different styles of legal systems as equivalent regarding the functions they serve, ie transparency, judicial accountability and control. See Ralf Michaels, The Functional Method of Comparative Law. In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 339-382, at 341-342.

587 Ezekiel Emanuel, The Evolving Norms of Medical Ethics. In Ronald M Green, Aine Donovan and Steven A Jauss (eds), *Global Bioethics: Issues of Conscience for the Twenty-First Century*. Oxford: Clarendon Press, 2008, pp 53-76, at 54.

today.[588] The situation may not be as amorphous as Emanuel sets out in his analysis. In Singapore, medical law continues to place considerable emphasis on beneficence, or acting in the best interests of patients.[589] As for biomedical research, the 'founding principles' of bioethics (i.e. autonomy, beneficence, nonmaleficence and justice) continue to hold sway in the minds of researchers, research administrators and regulators.[590] This could perhaps be said in very general terms across the jurisdictions of my study, although there will undoubtedly be some exceptions. In fact, my initiation into the lifeworlds of medical ethics and bioethics could be described as encounters with complex structures of principles and their relationship *inter se*.

Let me try to give a 'snapshot' of bioethical knowledge that applies in the day-to-day operation of the Secretariat. There is now a general expectation that any decision made by a biomedical research policy-body or an IRB be grounded in one or more ethical requirements set out in a number of key documents. Some documents are specific to particular types of biomedical science and technology, such as UNESCO's Universal Declaration on the Human Genome and Human Rights.[591] The principles set out in these documents may overlap, and the extent of their relevance often depends on the specific circumstances of each case. Within the institution of the BAC, an ethical doctrine centered around a number of ethical principles gradually took shape. Key principles include justice,[592] respect for human health, welfare and safety (or

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588 *Ibid*, at 65-66, and 74.

589 Mental Capacity Act enacted in 2008 is illustrative of this. See Mental Capacity Act, Cap 177A of Singapore (2010 Rev Ed), and Office of the Public Guardian, *Code of Practice: Mental Capacity Act 2008.*

590 Fieldnotes dated 17 January 2008 (meeting with IRB administrators and researchers), 12 August 2008 (meeting with regulators), and 26 May 2009 (meeting with researchers).

591 United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on the Human Genome and Human Rights*, 1997.

592 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research*, 18 April 1979 (the 'Belmont Report').

beneficence),[593] respect for the human body, religious and cultural perspectives and traditions (i.e. a broader reading of beneficence),[594] respect for free and informed consent (or autonomy),[595] respect for vulnerable persons (autonomy and justice) and respect for human dignity.[596] Apart from the international domain, there are also important normative documents by regional and professional bodies.[597] The diversity and complexity of ethical structures that have arisen from these principles led some to conclude that there are different 'models' to policy decision-making in biomedical research,[598] and calls for greater harmonization by key international organizations such as the World Health Organization.[599] The strong normative linkage between research ethics and medical ethics (and medical law) cannot be omitted, as the latter has been an important source of ethical content and aspirations. The upshot of this intricate display of pervasive ethical structures is to highlight the basis of 'commonality' by which comparisons are made in bioethics. Indeed, any comparative law project relating to biomedical science and technology will very likely be seriously wanting in propriety and legitimacy unless it has been undertaken with an appreciation of these ethical structures and their influence on key actors that include bioethicists,

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593 Nuremberg Military Tribunal. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law* No 10, Vol 2. Washington, DC: US Government Printing Office, 1949, pp 181-182 (the "Nuremberg Code"), Articles 4 and 5.

594 See documents of the United Nations General Assembly: *Universal Declaration of Human Rights* 1948 (Article 26), *International Convention on Economic, Social and Cultural Rights* (Articles 1.1, 2.2 and 15), and *International Convention on the Elimination of All Forms of Racial Discrimination* 1965 (effective from 1969). See also UNESCO's *Declaration on Race and Racial Prejudice* 1982, Articles 1 and 5.

595 World Medical Association, *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, 22 October 2008 (as amended), at paragraph 24.

596 See Articles 1, 2, 6, 10, 11, 12 and 15 of the UNESCO's *Universal Declaration on the Human Genome and Human Rights* 1998.

597 Those that are commonly referred to include Council of Europe's *Convention for the Protection of Human Rights and Dignity of Human Beings with respect to the Application of Biology and Medicine* 1997, and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (1982; 2002 updated) of the Council for International Organizations of Medical Sciences (CIOMS).

598 Bartha M Knoppers, Emily Kirby and Rosario Isasi, Genetics and Stem Cell Research: Models of International Policy-making. In John M Elliott, W Calvin Ho and Sylvia SN Lim (eds), *Bioethics in Singapore: The Ethical Microcosm*. Singapore: World Scientific, 2010, at 133-163.

599 Alex Capron, American Law and the Governance of Research Ethics: Time for International Change (2010) *Singapore Academy of Law Journal* 22: 769-784.

research administrators, biomedical research regulators and policy-makers, researchers and physicians.

The most direct implication of these ethical structures is in constituting a framework within which certain actions are determined to be ethical or unethical. As the 'fit' among these various structures is not seamless,[600] there is a significant number of 'grey areas' where the ethical acceptability of certain actions remains unclear (for instance, the provision of compensation for participation in clinical trials remains a controversial subject). Nevertheless, the construction of 'ethical' within such a framework is arguably similar to the way in which arbitrage serves as a framework in Hirokazu Miyazaki's study.[601] Within the 'framework' of arbitrage, transactions that are speculative in character have been perceived to be risk-free up to a point. As we have seen, the work of the BAC, no less its comparative projects, has been closely connected with mapping relationalities and meaning creation within this framework of bioethical narratives.

4.8 Incommensurability and Solidarity

I go further by arguing that it is within a framework either developed from ethical knowledge or otherwise constructed with embodied principles that comparison was made by the BAC in these projects. The construction of a broader normative platform or premise seemed obviously necessary as a first step to effecting comparison. More precisely, it enables the application of

600 It is even more difficult to say whether different ethical structures could come together as a coherent system as some structures are opposed, with no prospect of inter-dependence.

601 Hirokazu Miyazaki, Between arbitrage and speculation: an economy of belief and doubt. *Economy and Society* (August 2007) 36 (3): 396-415, at 402.

what has appeared to me to be syllogistic logic – a mode of reasoning that Geoffrey Samuel considers to be quite possibly one of the most evident techniques (in combination with analogy) in legal method and legal reasoning.[602] The central logic to this technique and device relates not only to the construction of a genus (i.e. the major normative premise) and a species (the minor descriptive premise), but also the association between the two that generates concrete experience, such as in the division between things *in genere* and *in specie*.[603]

The application of syllogistic reasoning in law towards the construction (more often perceived as 'derivation' in a policy setting) of a rule or canon characterized by generality and normative weight in the BAC's comparative projects is intended in part to overcome claims of incommensurability. As the caveats to the comparative tables on oocyte donation and human-animal combinations make clear, the BAC's interest is not to cross "epistemological boundaries".[604] Unlike superstructures such as the shared legal framework of the European Union, these comparative projects, while directed at producing some rule of similitude, are not directed as harmonization.[605] But as we have seen, such ethical superstructures have been drawn upon in the BAC's comparative projects for the more limited purpose of creating a standard that

602 Roman jurist Alfenus was said to have deployed this technique in addressing issues like: "Does a boat actually exist or is it simply a matter of individual planks? Does society exist or are there only individual men and women?" This technique has contributed to the development of analytical devices in law such as subrogation, fundamental to current legal understanding of risk substitution and transfer. See Geoffrey Samuel, Comparative Law and the Legal Mind. In Peter Birks and Arianna Pretto (eds), *Themes in Comparative Law: In Honour of Bernard Rudden*. Oxford and New York: Oxford University Press, 2002, 35-47, at 37-38.

603 *Ibid*, at 44.

604 Construction in comparison is implied in Pierre Legrand's argument that "even the most sophisticated comparative analysis originating from one tradition will, ultimately, fail to cross epistemological boundaries". Pierre Legrand, Alterity: About Rules, For Example. In Peter Birks and Arianna Pretto (eds), *Themes in Comparative Law: In Honour of Bernard Rudden*. Oxford and New York: Oxford University Press, 2002, 21-33, at 22. He considers there to be an essentially irreconcilable difference between the common law and civil law systems. In relation to his 'rule model', the civil law is understood to operate on an 'if-then' basis whereas the common law adopts an 'as-therefore' approach (at 28).

605 Pierre Legrand, The same and the different. In Pierre Legrand and Roderick Munday (eds), *Comparative Legal Studies: Traditions and Transitions*. Cambridge: Cambridge University Press, 2003, 240-311, at 294.

not only defines a space for action locally, but also justify these actions, if taken, globally. In other words, the intermediatory role of the BAC is closely linked to the substantive purpose of its comparative projects. However, the extent to which ethical superstructures are drawn upon and incorporated into local policies and standards depends on situational and political factors. We have considered some aspects of this, and will consider other aspects further on in this dissertation.

There is another critical role that ethical superstructures have played in the comparative projects of the BAC. Within a principled framework, the purposes behind policy actions of foreign jurisdictions are discoverable (or imputable). It is on this basis that James Whitman argues that the burden of incommensurability should not completely overwhelm comparative efforts.[606] Referring to Max Weber, he indicates that human action is not only purposive (*zweckrational*), but also consistent with large normative commitments (*wertrational*), concerned with upholding tradition (*traditional*) or emotional and primordial (*affektuell*) commitments. Hence human actions are always accessible to our understanding. He proposes for focus to be on action, rather than worry about how we understand persons, texts or cultures.[607] Referring to the hermeneutic approach of Hans-Georg Gadamer in addressing the problem of 'understanding' the 'other',[608] he encourages comparatists to direct their attention on *Vorverständnis* (or pre-understanding, the unarticulated, taken-for-granted assumptions that underlie the law), which may be inarticulate and difficult to communicate, but not impossible. In his view, this understanding need not be

606 Whitman considers over-emphasis of incommensurability to be an excess of Romanticism. Hence he disagrees with Pierre Legrand's views on non-transplantability, and refers to the spread of sexual harassment law into Continental Europe as illustration. See James Q Whitman, The Neo-Romantic Turn. In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 312-344, at 336-339.

607 *Ibid*, at 323-324.

608 Hans-Georg Gadamer (translation and revised by Joel Weinsheimer and Donald G. Marshall), *Truth and Method*. London and New York: Continuum, 2004.

"total" as the concern of comparative law is not in explaining the total culture, but in normative justifications and tacit assumptions.[609]

Indeed, incommensurability does not appear to be too much of a concern for comparative projects in bioethics. While the importance of social, cultural or historical differences is almost always recognized, they are not taken as amounting to incommensurability. In fact, the general mindset of many bioethicists and policymakers that I have encountered does not appear to be dissimilar from the *common core approach* in comparative law. This approach has been traced to the Cornell Hypothesis, which postulates that there is a common core of legal concepts and precepts shared by some or even most of the world's legal systems. On incommensurability, the authors of *Schlesinger's Comparative Law* agrees with Whitman that claim of 'incomparability' or unbridgeable differences should not be assumed, as deconstruction of legal ontology (such as abstract legal categories like 'contract', 'tort' and 'unjust enrichment') often leads to the discovery of fundamental analogies hidden behind apparently irreconcilable differences.[610]

The constructivist essence of the common core approach has been an important basis for the comparative projects of international organizations and academic institutions, whose works (as we have seen) have had a significant impact on the BAC. Take for instance, the IFFS surveillance reports. Governance systems on ARTs are regarded as open and complex aggregates

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609 Whitman argues: "'Law' is not best thought of as a rooted set of cultural facts that can be 'understood' only in cultural context. 'Law' is best thought of as an activity that aims at normative justification of certain human acts and of the exercise of the authority of some humans over others. Different societies unquestionably offer different normative justifications for different acts; moreover, different societies work with different sorts of tacit Vorverständnis that bear on the operation of their 'law'…Nevertheless, a set of normative justifications and tacit assumptions is not the same thing as a total 'culture'." See James Q Whitman, The Neo-Romantic Turn. In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 312-344, at 343-344.

610 *Ibid*, at 99. A similar deconstruction is considered necessary when comparing professionalized with less professionalized law (at 97).

of laws and pseudo-legal elements, with the surveyors themselves serving as geographers in tentative area-by-area survey or as zoologists dealing with the problem of classifying legal systems.[611] Arguably, the presence of ethical principles and superstructures have inspired and driven a comparative mindset in the study of bioethical issues. There is also a sense of what Mark Freedland refers to as a belief in "the possibility and importance of legal solidarity and community".[612] This mindset and belief encourages one, when faced with a problem, to look beyond the self and to deliberate on the other as an equal or perhaps even an example. The effect could perhaps be taken to be similar to the way in which the European Union's *Product Liability Directive* encouraged courts in the UK, France and Germany to examine through comparison the substantive and procedural aspects of contaminated blood transfusion.[613] Referring to European Union law more generally, Guy Canivet observes that fundamental principles embedded within the legal framework has been intrinsic to actualization of the European order by French courts through the gradual internalization of common values.[614] This was said to be similarly the case in Italy.[615]

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611 *Ibid*, at 177 and 214. Classifying is seen as the ultimate purpose of comparative work (at 258-260).

612 Mark Freedland makes this remark in relation to the personal preference of the comparer in realizing leal solidarity and community within the European region. Mark Freedland, Introduction: Comparative and International Law in the Courts. In Guy Canivet, Mads Andenas and Duncan Fairgrieve (eds), *Comparative Law Before the Courts*. London: The British Institute of International and Comparative Law, 2004, pp xv-xxvi, at xxv.

613 Michael Brooke QC and Ian Forrester QC, The Use of Comparative Law in A & Others v National Blood Authority. In Guy Canivet, Mads Andenas and Duncan Fairgrieve (eds), *Comparative Law Before the Courts*. London: The British Institute of International and Comparative Law, 2004, pp 57-83.

614 Guy Canivet, The Use of Comparative Law Before the French Private Law Courts. In Guy Canivet, Mads Andenas and Duncan Fairgrieve (eds), *Comparative Law Before the Courts*. London: The British Institute of International and Comparative Law, 2004, pp 181-193, at 184-185. See also Roger Errera, The Use of Comparative Law Before the French Administrative Law Courts. In Guy Canivet, Mads Andenas and Duncan Fairgrieve (eds), *Comparative Law Before the Courts.* London: The British Institute of International and Comparative Law, 2004, pp 153-163.

615 Aldo Sandulli, The Use of Comparative Law Before the Italian Public Law Courts. In Guy Canivet, Mads Andenas and Duncan Fairgrieve (eds), *Comparative Law Before the Courts*. London: The British Institute of International and Comparative Law, 2004, pp 165-178.

In more practical terms, a belief in solidarity and a comparative mindset incentivizes social interaction and discursive engagement. Expressing a view similar to Lord Bingham's, Guy Canivet indicates that legal cultures are influenced by factors external to them, even if such influences are moderated or subtle.[616] It is critical not to underestimate this belief in solidarity, which I find to be pervasive in biomedical research, healthcare and bioethics communities. It is a basis of sociality and defines the respective worldviews in communal terms where no researcher, physician or bioethicist considers herself or himself as acting alone. This is perhaps the strongest argument against any claim of incommensurability in a strong sense. Indeed, when I attempted to explain my concern with incommensurability in the comparative projects of the BAC, it was either politely dismissed or met with various expressions of incomprehension.[617] Patrick Glenn explains that human communication precludes any strong claim to incommensurability.[618]

Even if we should reject incommensurability in many instances, one should be wary not to confuse the drawing of relationality with *carte blanche* discursive displacement. It is often difficult to pinpoint the exact extent of borrowings or influences from external sources. As we have seen in the earlier chapters, wholesale transplantation of biomedical research regulatory practices or mindset has not and is unlikely to occur. However, external factors and pre-existing

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616 Guy Canivet observes: "The French private law judge is no longer – if he ever really was – considered as the 'mouth that produces the words of the law' (in the famous words of Montesquieu). He is commissioned to adjust law to the values of his society…local and foreign legal cultures constantly interact… *no legal culture is exclusively inward-looking…*" Guy Canivet, The Use of Comparative Law Before the French Private Law Courts. In Guy Canivet, Mads Andenas and Duncan Fairgrieve (eds), *Comparative Law Before the Courts*. London: The British Institute of International and Comparative Law, 2004, pp 181-193, at 182-183 (emphasis added).

617 Fieldnotes, 20 August 2008 (Secretariat).

618 H. Patrick Glenn, *Legal Traditions of the World: Sustainable Diversity in Law*. Oxford and NY: Oxford University Press, 2007 (3rd ed.), at 45.

norms have been sufficiently influential to displace any strong-form notion of autopoiesis.[619] What remains clear, at least from my research, is the lawyer as technoscientist, operating within a problem-solving modality and accompanying engineering mentality where "social ends could be accommodated…by a highly rationalized, technical means-ends framework that would calibrate law according to changing social conditions."[620] It is realistic, functional and practicable; and not directed at political critique or philosophical contemplation. In other words, where anti-formalism holds sway in comparisons undertaken within academia,[621] formalism (or Kennedy's 'right-wing' anti-formalism)[622] appears to dominate comparative work in the policy environment. Of course, neither the BAC nor its Secretariat would think of their work as apolitical. Rather, they do not consider politics to be the business of the BAC, which has afterall been constituted by the government to provide *expert* advice. Hence the *technocratization* of comparative projects is a means by which the BAC distant itself from politics. It is also a way of attaining 'objectivity', which in turn advances the legitimacy of its recommendations with both the government and the public.

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619 Although Cotterrell appears to be critical of Alan Watson's notion of legal transplants as too simplistic, since the importation of legal ideas and practices into a legal system tends not to be as 'easy' as Watson seems to suggest, it is unlikely that Cotterrell would agree with Pierre Legrand's application of autopoiesis in a strong sense, where legal or other institutional cultures are impenetrable as a normatively self-sufficient discourse. See Pierre Legrand, European Legal Systems are not Converging, (1996) 45 *International and Comparative Law Quarterly* 52; Roger Cotterrell, Comparatists and Sociology. In Pierre Legrand and Roderick Munday (eds), *Comparative Legal Studies: Traditions and Transitions*. Cambridge: Cambridge University Press, 2003, pp 131-153, at 146-150.

620 Annelise Riles, Property as Legal Knowledge: Means and Ends (2004) *Journal of the Royal Anthropological Institute* 10:775-795, at 785.

621 David Kennedy observes that anti-formalism became mainstream from the 1950's, although within this camp, there was a distinction between those who emphasized technical characteristics and universal or shared features, as opposed to those who emphasized cultural characteristics and differentiatedness. David Kennedy, The methods and the politics. In Pierre Legrand and Roderick Munday (eds), *Comparative Legal Studies: Traditions and Transitions*. Cambridge: Cambridge University Press, 2003, pp 345-433, at 403-406.

622 *Ibid*, at 417. However, 'right-wing' anti-formalists here are less likely to view the law as autonomous, going by the features that Kennedy attributes to this camp.

The constructivist nature of functional comparison directed at undermining differences and at system building provides a simple explanation for this lack of regard for the 'social'. Thinking further however, the 'social' has always been there, but not apparently so. Comparative projects are important means by which policymakers 'make sense' of the policy terrain. This policy terrain is the social totality that becomes the substrate for technocratic structuration. As we have seen, both the policy issues and responses are extricated from the same social bedrock. Structuration renders definition and confers meaning. It further enables association to be made, thereby creating a sense of solidarity and legitimacy. Hence an expression of 'making sense' is making comparison, and in respect of which ethics and law are the tools by which social structuration is achieved. Amidst social construction, the tools are most evident, and brackets out the 'social'.

4.9 Relationality in Comparative Tables as Policy Devices

As a matter of approach, the comparative projects of the BAC that culminated in the comparative tables on oocyte donation and human-animal combinations do not fit neatly into Dannemann's three major stages of comparative enquiries; these being selection (of what will be compared), description (of the law and its context in the legal systems under consideration), and analysis.[623] The assemblage of 'relevant' jurisdictions could be broadly regarded as 'selection' but not in the sense of a formal quantitative sampling. This 'selection' through abstraction is a matter of construction that deploys ethical and legal knowledge as resource and tool. More importantly,

[623] Gerhard Dannemann, Comparative Law: Study of Similarities or Differences? In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 383-419, at 406.

the ‘selection’ process is not simply a matter of grouping things together based on certain characteristics, but it has been a relational exercise from the start.

Relationality occurs at various levels. First, ‘selection’ involves correlating relations of governance at the level of jurisdictions to a broader ethical superstructure, most apparent in the body of international and transnational normative documents on bioethics (including medical ethics). In fact, the term ‘correlation’ is surprising appropriate as it suggests co-production in the association between these relations of governance within a broader ethical framework, although it is rarely the case that one holly defines the other in multi-factorial analysis. This association further suggests the reason for appeal to universalism and foundationalism in many comparative projects on bioethical policy, quite unlike a strict Weberian statist approach for instance (although this aspect is nevertheless present).[624] Second, ‘selection’ is also a matter of relationality among the jurisdictions compared. In a policy environment, this could be described as ‘benchmarking’, so that where Singapore’s position is said to be shared with Countries X and Y, for instance, a generally common ethical standard is seen to apply in all three jurisdictions. It is further crucial to recognize that this association cannot be simply claimed, but must be substantiated in order to have credibility. In some sense, it is like a currency peg, whereby an exchange rate of a country is closely tied to that of another. Once the association is made, the ethical policies of Countries X and Y will continue to have influence, although the extent may vary depending on a variety of factors. This aspect of relationality is perhaps most evident at the third level of relations between the ethical standards producer and those upon whom these standards apply. At a meeting between the BAC and researchers, a Japanese researcher queried if

[624] Ahmed White, Max Weber and the Uncertainties of Categorical Comparative Law. In Annelise Riles (ed), *Re-thinking the Masters of Comparative Law*. Oxford and Portland (Oregan): Hart Publishing, 2001, pp 40-57, at 43.

bioethical policies in Singapore are too 'western'.[625] I was similarly asked by a regulator if the BAC is being too 'westernized' in putting emphasis on the principle of autonomy in requiring specific consent for certain types of research.[626] On further enquiry, I discovered that these sentiments arose from the relationality that has been established between bioethical policies in Singapore with those of key 'western' countries, especially the UK and the US. Another colleague in bioethics from Taiwan told me that he appreciated what appeared to him to be a more open and less hierarchical bioethical setup (at least in a hospital environment) in Singapore owing to 'the British influence'. To some degree, there is some truth to these perceptions that there is in general a strong association between ethical policies in Singapore with those in the UK, for instance. There is a clear policy rationale for this stance, but it would be misleading to think of Singapore's policies as being entirely at one with those of the UK (or any other country), as we shall see in the next chapter.

I want to elaborate on positional relationality at the level of jurisdictions that the BAC's comparative projects establish. While these projects could explain differences and similarities with a view to 'learn' from other legal systems as a more conventional purpose usually attributed to comparative work, this was not the most important purpose. Instead, comparative tables are intended to be artifacts of relationality generated through comparison. We have considered this in the manner that comparison constructs and attributes positionality. In addition, comparative tables create the normative standards that govern oocyte donation and human-animal combinations. Lorraine Daston describes an instructive encounter with the Ware Collection of Blaschka Glass Models of Plants (or Glass Flowers) at the Harvard Museum of Natural History.

625 Fieldnotes, 26 May 2009.
626 Fieldnotes, 26 July 2010 (MT).

She asks:[627] "What kind of things are the Glass Flowers? Much of their fascination derives from their unclassifiability – itself a paradox, since they were made and are still displaced in order to demonstrate post-Darwinian phylogenetic botanical classification. They are at once undeniably artificial and flawlessly natural…" Daston then observes that while possessing some degree of mass appeal, these flowers are neither valued by botanists nor artists.[628] She concludes that these artifacts have a representational meaning over and above their physical form, but what exactly the meaning is has not been articulated.[629]

Like the Blaschka Glass Flowers, comparative tables are unlikely to satisfy the 'superior people' (to borrow Daston's language) of comparative law or socio-legal scholarship. As with other comparative tables, they classify through categorization, but defy any meaningful categorization themselves. Whereas Daston considers this to be some form of non-reductionist aesthetic communication, I understand this as an 'inner logic' that the BAC's comparative tables possess. These comparative tables were developed for the specific purpose of constructing, correlating and communicating relationalities within the broad narrative of 'bioethics'. The representations that they encapsulate have been taken to be 'standards' that (co-)relationalities generate. However, the specificity in function of these tables precludes their broader application as 'generalizable knowledge' and further renders them non-representational. In this sense, comparative tables are akin to Annelise Riles's 'collaterals' in her study of financial derivatives in Japan. Riles provides as illustration a scenario whereby a trader at Paribas Bank agrees with a trader at Sanwa Bank to swap a certain amount of currency at a certain price in a year's time,

627 Lorraine Daston, The Glass Flowers. In Lorraine Daston (ed), *Things That Talk: Object Lessons from Art and Science*. New York: Zone Books, 2004, pp 223-254, at 225.

628 *Ibid*, at 252: "The fact that thousands of tourists come to gawk at the models every year does not improve their standing in the Republic of Letters. Superior people do not visit the Glass Flowers."

629 *Ibid*, at 254.

pursuant to a swap agreement.[630] As assurance that Sanwa Bank will be able to meet its future obligation, Sanwa Bank would provide Paribas Bank with collateral. Sanwa's collateral will "precisely stand for, be the measure of, the extent to which it [Paribas Bank] can compel Sanwa to act as promised",[631] and thereby lower the greater information needs ('messy details') that Paribas Bank would otherwise be faced with. In ethnographic terms, Riles argues that the collateral is "an explicit modality of (temporary delineated) politics" and has "the same kind of political instability and ambiguity that characterizes the debt-like relations of the swap."[632] She adds that a collateral is then "both a technology and a political problem, both a means to an end and a special kind of relationality [which]…raises a problem of an attenuated, seemingly interminable (albeit ultimately finite) present of mutual entanglement."[633] The BAC's comparative tables share a similar kind of political instability and ambiguity in the instrumental relationalities that they draw. As a technology and a political problem, I would prefer to think of these characteristics as manifestations of an inner logic. In policy process, the inner logic of comparative tables is a crucial means by which external information, values and material factors are translated into a policy environment and internalized. This logic confers on comparative tables the capacity to be utilized as normative tools in public policy. It is to this 'inner logic' as a form of technocratic knowledge that we now turn.

630 Annelise Riles, Collateral Expertise: Legal Knowledge in the Global Financial Markets. *Current Anthropology* (December 2010) 51 (6): 795-818, at 801.
631 *Ibid*, at 802.
632 *Ibid*.
633 *Ibid*.

4.10 Inner Logic of a Technocratic Knowledge Function

As Wittgenstein observes, it is easy to assume that comparison produces 'objective' (or generally applicable) knowledge on the subjects compared rather than knowledge that is most immediately useful only for the comparatist.[634] Jan Komárek's critique of Mitchel Lasser's *Judicial Deliberation* is illustrative of this. Komárek considers *Judicial Deliberations* to lack conceptual clarity as it does not sufficiently account for conceptual debates in omitting the important interplay between the Cour de cassation and the legislature, as well as what amounts to 'law' for instance, and for deriving "his understanding of the status of la jurisprudence from a selective 'literary analysis' of the rhetorical use of the term, disentangled from its conceptual meaning."[635] Komárek also points out that in emphasizing the 'ethic of argumentative transparency', Lasser inappropriately underplays the institutional control of judicial power in the US. He considers the US Supreme Court to be not so much making law than articulating what Congress could not, and further observes that Congress has significant control over the jurisdiction of the federal judiciary and its overall design, particularly through 'jurisdiction-stripping' legislation.[636]

Komárek's critique lacks foundation in failing to recognize that Lasser already makes clear that his account is but one aspect, and not the only narrative of the French judicial system. In addition, his approach is pragmatic and essentially directed at specific issues within the

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634 Ludwig Wittgenstein (edited by Rush Rhees and translated by A C Miles), *Remarks on Frazer's Golden Bough*. Swansea: The Brynmill Press, 1979. Wittgenstein argues (at 5e): "Even the idea of trying to explain the practice – say the killing of the priest-king – seems to me wrong-headed. All that Frazer does is to make this practice plausible to people who think as he does. It is very queer that all these practices are finally presented, so to speak, as stupid actions…Frazer cannot imagine a priest who is not basically an English parson of our times with all his stupidity and feebleness."

635 Jan Komárek, Questioning Judicial Deliberations. *Oxford Journal of Legal Studies*, Vol 29, No. 4 (2009), pp 805-826, at 810.

636 *Ibid*, at 814-815.

comparative boundaries drawn. Interestingly, Komárek primary argument that the Cour de cassation's legitimacy depends on the supremacy of the legislature and its recognition that it is the lower courts that come into active contact with 'real-life' situations does not differ greatly from Lasser's analysis, even if Komárek is correct in his observation that Lasser puts greater emphasis on the institutional structure of the French legal process.[637] This is more a question of emphasis. The assessment that *Judicial Deliberations* lack conceptual clarity is also fallacious in his assumption that comparative findings could be placed on the same footing as empirical research.[638] While one can learn a lot about the French judicial system from *Judicial Deliberations*, it is a knowledge that is gained through comparison with the US Supreme Court. Hence *Judicial Deliberations* is not so much about the French judicial system *per se*, but is more critically a work about the US Supreme Court and how the Cour de cassation should properly be understood beyond the narrow narrative of the US judicial system.

Wittgenstein's critique, as well as Lasser's more contemporary contribution, provides the occasion to reflect further on what the BAC's comparative tables do in a policy environment. We have seen that these comparisons create relationalities within a broader narrative (or perhaps varied and fragmented narratives) of 'bioethics'. Taken in isolation, these albeit hypothetical (as yet unproven causal) explanations advanced in comparison could be instructive as a form of general knowledge. In policy work, they are not only means of self-knowledge (through mapping of relationalities, as we have seen), but embody as well as perpetuate a composite form of rationalities. As Hal Colebatch and others have observed, policy work is largely concerned with

637 *Ibid*, at 813.

638 As Annelise Riles explains, this also accounts for the difference in focus between comparative lawyers and social-legal scholars. See Annelise Riles, Comparative Law and Socio-Legal Studies. In Mathias Reimann and Reinhard Zimmermann (eds), *The Oxford Handbook of Comparative Law*. Oxford and New York: Oxford University Press, 2006, pp 775-813, at 783-785.

solving problems and the application of known techniques of governing to areas of concern.[639] Cost-benefit analysis has been a dominant form of Weberian-styled rationality applied in the ordering and internalization of external information and factors. The reductionism in rendering calculable and the rigidity in dualistic categorization (or perhaps more appropriately compartmentalization) entailed in this form of rationality has been criticized by Ahmed White.[640] He considers this inner logic of Weberian comparativism to be problematic as it has a "neo-Kantian tendency toward dualism and formal rationalism, and eventually conservative, a-historical, and altogether reified inquiry."[641] It is not difficult to recognize the importance of historicity and value transparency in comparison.[642] However, it does not appear to me that Weber failed to recognize this in his discussion of competing rationalities in action-orientations. Instrumental or means-and-ends rationality is but one of four possible action-orientations in his exposition of rationalization in the economic sphere.[643] Weber makes clear that all four types of action-orientations (values and traditions being the other ideal typification of causal rationalities, apart from the instrumental and affective) could have an influence on a social actor. More critically, one should remain mindful that these four action-orientations are ideal-typifications

639 Hal Colebatch, Robert Hoppe and Mirka Noordegraaf, Understanding Policy Work. In Hal K Colebatch, Robert Hoppe and Mirko Noordegraaf (eds), *Working for Policy*. Amsterdam: Amsterdam University Press, 2010, at 6.

640 Mitchel Lasser offers a similar critique of Roscoe Pound's comparative work, through which "Pound proposes a unified and universalizing version of comparative legal history that presents all Western legal history as advancing through a handful of "stages of development". See Mitchel Lasser, Comparative Readings of Roscoe Pound's Jurisprudence (2002) *American Journal of Comparative Law* 50: 719-752. The cyclical approaches that Lasser finds in Pound's work (at 724-725) could be a consequence of limitations to typification. Certain characteristics might have been predominant in one of the five stages of legal development, but not entirely absent in the other stages. Differences could well be largely a matter of scaling or degree rather than one of development progression, as Lasser notes.

641 Ahmed White, Max Weber and the Uncertainties of Categorical Comparative Law. In Annelise Riles (ed), *Re-thinking the Masters of Comparative Law*. Oxford and Portland (Oregan): Hart Publishing, 2001, pp 40-57, at 53.

642 *Ibid*, at 56.

643 Weber famously postulates that social action, like all action, may be oriented in four ways: instrumentally rational (zweckrational), value-rational (wertrational), affectual and traditional. See Max Weber (edited by Guenther Roth and Claus Wittich, eds), *Economy and Society: An Outline of Interpretive Sociology*, Vol 1. Berkeley, Los Angeles and London: University of California Press, 1978, at 24-26.

and hence essentially heuristic and analytical constructs. Arguably, such an analytical approach that places considerable emphasis on purpose and intentionality signifies Weber's rejection of reductionism for a multi-factorial analysis where values, tradition and emotions have just as crucial a contribution as means-and-ends calculation. Hence in *The Protestant Ethic and the Spirit of Capitalism*, Weber famously argues the 'elective affinity' between rationalization in an ascetic religious ethic with that in capitalist enterprise. His postulation relates to a historical association, not a causal connection, with the intent of demonstrating that the social actions of this religious community could bear dual rationales – value-based and instrumental. To a similar effect, Weber explains that punctuality of civil servants is not merely a consequence of rational calculation, but more importantly as a value (that indicates a sense of responsibility for instance).[644] More recently, Jürgen Habermas re-conceptualizes Weber's rationalization into three distinct complexes of science (theoretical reason), morality or ethics (practical reason) and art (aesthetic-expressive reason).[645] Each is aligned with a different interest: cognitive-instrumental rationalization in science that relies on propositional truth for its claim to validity, moral-practical in the ethical complex that relies on normative rightness for validity, and aesthetic-expressive that relies on subjective truthfulness. While labor is taken to embody instrumental rationality, interaction could provide transformative emancipation from the iron-cage of instrumental disenchantment through communicative action, which continuously opens up new inter-subjective spaces.

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644 Weber argues that punctuality, like duty, is a critical aspect of the ideal-typical status ethic of civil servants. See Max Weber (edited by Guenther Roth and Claus Wittich, eds), *Economy and Society: An Outline of Interpretive Sociology*, Vol 2. Berkeley, Los Angeles and London: University of California Press, 1978, at 956-958.

645 Jurgen Habermas (trans. Timothy McCarthy), *The Theory of Communicative Action: Reason and the Rationalization of Society*, Vol 1. Cambridge: Polity Press, 1984, at 164-165. While there may be some basis for this reading of Weber's empirical sociology, Austin Harrington argues that Weber's interpretation of modernity shows greater cultural differentiation. See Austin Harrington, *Value-Spheres* or 'Validity-Spheres'?: Weber, Habermas and Modernity (2000) *Max Weber Studies* 1: 84-103.

The 'inner logic' of comparative projects of the BAC, including the resulting comparative tables, demonstrates the operation of all four action-orientations put forward by Weber. As public policy, the communicative character in the overarching goal of linking interaction and discourses in ways that enhances inter-subjective space is evident. Whether this inter-subjective space amounts to 'new' knowledge is, as we have discussed, an ancillary concern at best. More critical for our purpose are the non-instrumental rationalities that compose this shared space. In specifically incorporating, for instance, an 'ethical' dimension to the funding and practice of science, rationalization based on values, tradition and (to a lesser extent) emotions are re-invigorated, at times countering a scientific instrumental rationalism that Weber regards as unstoppable.[646] The BAC's work could be viewed as a re-calibration of weightage in motivational rationalities, given that many contradictions that we witness in the politics of biomedical science arise from the interplay of different rationalities taken from standpoints that could be economic or political, ethical or aesthetic. This could also be seen as a form of communicative resistance to the disenchantment of scientific (instrumental) rationality, bearing in mind that 'ordering' and rationalizing through issues in public policy could never be entirely value neutral. And again, what is value-based could nevertheless have an instrumental character. Formal rationalization in terms of logical consistency in ethical content and systems through the application of rules or procedures has an instrumental character as it seeks to regularize certain actions so that they are always goal oriented and purposeful.

646 Max Weber, Science as a vocation. In Wolfgang Schirmacher, *German Essays on Science in the 20th century*. New York: Continuum, 1996, at 223-237.

4.11 Conclusion

At the commencement of my fieldwork with the BAC Secretariat, documents were being prepared for an important meeting of the main Committee. Among these documents, the proto-Consultation Paper and its comparative tables on human oocyte donation and human-animal combinations were circulated ahead of the meeting for consideration and specifically marked for discussion. No explanation was needed as it was generally assumed that policy positions from outside of Singapore were available and relevant. This *praesumptio similitudinis* could be justified on at least two bases discussed in some detail above. First, certain international events contributed to the harmonization of issue-framing across jurisdictions and discursive spaces. Second, there already exists a rich pool of bioethical discourses at the time of my fieldwork. In addition, a quite separate global bioethical framework could be said to exist, especially in the form of international soft-law instruments and through the projects and advocacy of international organizations such as UNESCO and WHO. Taken together, this framework and bioethical discourses inform problematization. It is also within this composite structure that policy actions have to be developed in order to count as 'ethical'.

Comparison was undertaken by the BAC as a means of immersion into this discursive environment. Reaching 'upward' necessitated comparison to be undertaken at a normative level where de-contextualization and generalization are entailed. Prior to this exercise, detailed (albeit 'on the books') accounts of policy and regulatory positions from different countries (especially the 'core' jurisdictions) were garnered and analyzed. From a jurisprudential standpoint, this manner of abstraction and generalization appears to me to follow a Kelsenian tradition.

Undoubtedly, my own contribution to the comparative work also had the effect of steering comparisons in that direction. On the whole, the comparative process resembled the approach that comparative lawyers have been described to practice (as opposed to that of social-legal scholars). It was instrumental and pragmatic in attempting to meet certain policy goals, even if somewhat 'amateurish'. In addition, this approach was useful as a technocratic skill directed at 'making sense' of the issues and figuring out viable options. This is a constructive process, inherently communicative and functional (*ie* qualities that are arguably more amenable to policy generation than legal critique). In addition, it was directed at enabling comparison and so, primarily concerned with overcoming incommensurability in a strong sense.

While technocratic comparison could be viewed as comparing relations of governance in an 'objective' non-relational way, the comparative work of the BAC appears to work very much in the opposite direction. Comparison was needed to gain a degree of self-awareness in order to establish solidarity with other 'like-minded' jurisdictions. As we have seen, such self-awareness does not often tell us anything more about the comparatist. The most practical benefit of this exercise is that the solidarity achieved confers legitimacy on a policy if other jurisdictions that share this position are held in high regard. In normative terms, solidarity through positional association becomes the basis of standards, or 'international best practices'. These standards are by no means uniformly adopted or shared by every jurisdiction. Standards are normative platforms that enable communication across different discursive and social context, essentially by undermining and supplanting discursive and other differences, and by focusing on particular problems and functions (thereby operating somewhat like Mitchel Lasser's 'sliding scales'). Such a 'constructivist' approach is again conducive to a policy environment as not every issue is

(fundamentally or expediently) resolvable or reconcilable in the political domain. Differences are undermined through the drawing of normative and functional equivalence through (from the analytical standpoint of comparative law) syllogistic reasoning and analogy. While possessing an instrumental character, the analysis above makes clear that the 'inner logic' to comparative work in public policy involves more than one particular type of reasoning. Adopting a Weberian analysis, we have seen that reasoning by values and (medical) tradition have been as (if not more) influential as instrumental reasoning (particularly in the nature of means-and-ends calculability). Hence a policy stance that is 'irrational' under the scrutiny of instrumental reasoning could nevertheless be justified on the basis of fundamental values or local traditions.

Finally, making comparisons and evidence to that effect – especially in the form of comparative tables – are critical symbols of policy due diligence. Whether for discussions within the BAC or for meetings with researchers, religious group leaders, policy-makers or other stakeholders, comparative positions have always been provided. The artifact of comparison, such as a comparative table, would usually be the subject of discussion. As we have seen, comparative tables are relational and communicate through typification, but are in turn difficult to typify. And as the BAC has been responsible for its construction, it is often credited (through recognition) with a certain degree of 'expertise'. In the chapter that follows, we consider another secondary construct that comparison and their artifacts communicate. Perhaps as ubiquitous as comparison, the notion of risk has been an overwhelming concern of the BAC and similar bodies elsewhere. It is to this notion, and its relationship with ethics and law, that we now turn.

CHAPTER 5

PRECAUTION AND RISK KNOWLEDGES IN THE GIVING OF HUMAN EGGS FOR RESEARCH

Abstract

Technical risk assessments distinguish between quantifiable and unquantifiable risks. Quantifiable risks are kept 'private' within institutions whereas unquantifiable risks have a more 'public' character as 'ethical' risks. By closely examining the work of the BAC on human oocyte (egg) donation for stem cell research, I provide an account of how more sturdy relations are made visible through anticipatory knowledge and its presentation as a civic epistemology. Anticipatory civic epistemology in turn instills precaution as a rationality of governance. As a meta-legal principle, precaution also serves as an analytic for the study of epistemic contribution of legal discourses and processes. This account is important for providing a legal analytic of risk and a political technology of preparedness, drawing on notions of risk (and precaution) as a means of rationalization, a basis of sociality, a tool for social control, as well as a cause and consequence of institutions and institutionalization, and a technology of preparedness. In addition, it provides support for a relatively more pluralistic conception of risk (and its corollary, precaution) as arising from a 'common fund of knowledges', and thereby contrary to a more dominant and monolithic conception of risk.

5.1 Introduction

The subject of egg (technically referred to as 'oocyte') donation for research was a matter taken up by the BAC with a view to update the SC Report published in 2002. At that time, the primary concern was to establish a governance framework for embryonic stem cell research and its related technology, SCNT. Since then, the SC Report, alongside other reports of the BAC, served to establish a framework for ethical governance of biomedical research in Singapore. Any research in Singapore that involves a human subject, human tissue (unless in small completely de-identified quantity or as ethically certified commercial cell-lines) or personal information, will need to undergo ethics review by an IRB or a similar body prior to the commencement of the research. Ethics review ensures, among other things, that participation in research, whether as a research subject or through the contribution of biological material or information, presents minimal harm, is voluntary and on an informed basis. Ethically sensitive research, such as therapeutic cloning and hESC research that involves human embryos, is further subject to legal regulation and additional scrutiny by the MOH. The legislation on cloning and a set of regulatory guidelines on the use of reproductive technologies (the 'AR Directives') are the main regulatory instruments. Under the AR Directives, the explicit consent of the donor from whom the embryos were obtained must be taken, without inducement, undue influence or coercion, after comprehensive information has been provided to the donor. As we have earlier noted, the regulatory purview of the AR Directives is limited to hospitals and clinics that fall within the jurisdiction of the MOH.

A governance framework established by these regulatory devices together with the SC Report enables hESC research and cloning technology to proceed on a regulated basis. It did not in itself contribute to a 'gold rush' into these areas of research. The fact that certain jurisdictions in Asia, like Japan and Singapore, permit hES cell research and SCNT to be carried out, did not result in a major influx of researchers, whether from within or without these countries. Margaret Sleeboom-Faulkner[647] indicates that strict and 'rather un-transparent' regulation might have been a cause of the slow rate of the advance of Japanese hES cell research and SCNT, compared to other areas of research like mouse genomics. In the winter of 2005, the scandal in South Korea surrounding Professor Hwang Woo Suk gave emphasis to the shortage of eggs that are needed for research. This scandal contributed to further conservatism on the part of regulators in Japan and Singapore.[648] There has been increasing pressure to find a sustainable source. One solution encompassed the use animal oocytes, thereby giving rise to human-animal combinations, as we have considered in Chapters 2 and 3. The other possibility would be to increase the numbers of oocytes donated by women. One way in which this could be achieved is by offering incentives for women 'at-risk' (i.e. women suffering from infertility) – even healthy women – to contribute to research. The concern going down this route is the possibility of woman being coerced into undergoing a potentially risky procedure of hyper-stimulation and oocyte retrieval with no direct therapeutic benefit. As these risks were considered to be quite distinct from those relating to human-animal combinations, the BAC decided to address the subject of egg donation in a

647 Margaret Sleeboom-Faulkner, Debates on human embryonic stem cell research in Japan: minority voices and their political amplifiers, *Science as Culture* (2008) 17: 85-97.

648 For a discussion on related developments in South Korea, see: Leo Kim, Explaining the Hwang scandal: national scientific culture and its global relevance, *Science as Culture* (2008) 17:397-415; Sungook Hong, The Hwang Scandal that "shook the world of science", *East Asian Science, Technology and Society: an International Journal* (2008) 2:1-7; So Yeon Leem and Jin Hee Park, Rethinking women and their bodies in the age of biotechnology: feminist commentaries on the Hwang Affair, *East Asian Science, Technology and Society: an International Journal* (2008) 2:9-26; Tae-Ho Kim, How could a scientist become a national celebrity: Nationalism and Hwang Woo-Suk scandal, *East Asian Science, Technology and Society: An International Journal* (2008) 2:27-45.

separate report even though they relate to stem cell research. The flow of events that followed is similar to the approaches that the BAC adopted in its deliberation on human tissue and genetics. On 7 November 2007, public consultation commenced with a press conference and public distribution of the ED Consultation Paper.[649] A public meeting was convened on 22 November 2007 just before many Singaporeans would go away during the year-end school holiday. The public consultation ended on 7 January 2008, a day before public consultation on human-animal combinations commenced. On 3 November 2008, a report (the 'ED Report') with recommendations on the subject was published by the BAC.[650] Superficially, egg donation does not appear to be a difficult matter at all. At least, that was how the BAC initially considered the matter, and how the public still largely regards it. But the simplicity masks the many contradictions and paradoxes in the social arrangements as we know it. Developments since 2002 suggest a learning curve in ethics governance that is not limited to policy makers, but also for researchers, bioethicists and broader civil society. A means by which this 'learning' came about has been in the notion of 'risks' and the mechanisms put in place to address and assess them.

Iain Wilkinson explains that the concept of risk can be analyzed as a cultural prism, as it presents "opportunities to magnify specific contexts of rationalization so as to detail the social conditions, moral commitments, political movements, institutional arrangements and technical means by which these are made possible and are set upon their course."[651] In assuming that all knowledge is bound by its social and cultural context, I have adopted an ANT approach to the study of risk. On this basis, I take the view that risk is never fully objective but relates to realities that "involve

649 Bioethics Advisory Committee. *Donation of Human Eggs for Research: A Consultation Paper*. Singapore: Bioethics Advisory Committee, 2007.

650 Bioethics Advisory Committee. *Donation of Human Eggs for Research*. Singapore: Bioethics Advisory Committee, 2008.

651 Iain Wilkinson, *Risk, Vulnerability and Everyday Life*. London and New York: Routledge, 2010, at 26.

the reproduction of meaning and knowledges through social interaction and socialization and rely upon shared definitions…and can be viewed as assembledges of meanings, logics and beliefs cohering around material phenomena, giving these phenomena form and substance."[652] I also follow Stephen Hilgartner's study of 'risk objects' in that this must first entail a systematic examination of the construction of 'women' as 'objects', and then as 'risky' when linked to causal attributes of 'safety', 'inducement' and 'payment' as harms or danger in the ED Consultation Paper and the ED Report.[653] Concerns over 'safety' have generated its own category of 'health risks'. In this connection, the policies and ethical guidelines of the NAS (which has the NRC and the IOM as its constituent organizations) remains important to the BAC, as they have also been in relation to human-animal combinations. Concerns over 'inducement' and 'payment' fall within a broader category of ethical (and 'unquantifiable') risks. These risks are in turn set out within a larger anticipatory civic epistemology, which is arguably embedded in and made 'real' experientially by what Mariana Valverde and others term a 'common fund of knowledges'. This epistemic 'common fund' constructs and deploys 'risk' and (its corollary) 'precaution' as a hermeneutic means of framing social processes and imbuing events with historical, political and moral meaning. One such deployment has engendered 'risk' and 'precaution' as critical components to bioethical policies as a political technology of preparedness. We first consider the various conceptions of risks, and how they relate to the risk discourse in the BAC's documents on egg donation.

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652 Deborah Lupton, *Risk*. London and New York: Routledge, 1999, at 29 and 30.

653 Stephen Hilgartner. The Social Construction of Risk Objects: or, How to Pry Open Networks of Risk. In James F. Short and Lee Clarke (eds), *Organizations, Uncertainties, and Risk.* Boulder, CO: Westview Press, 1992, pp 39-53.

5.2 Risks Object Identification and Issues Framing

From early to mid-2007, work on preparing recommendations on egg donation was in full swing. Since that time, a broad notion of 'risk' has framed much of the BAC's discussion, deliberation and communication. At the outset, it recognized the possibility of exaggerated fears arising from the ethical scandal in South Korea involving Professor Hwang Woo-Suk, and was careful to avoid this. The riskiness of the egg retrieval process was a key concern. While everyone understood that some risk to health is entailed in egg donation, the challenge was in quantifying it. Hence, the BAC was concerned that an IRB may have difficulty approving research proposals that entail oocyte donation by women not undergoing fertility treatment, as donors would be put at health risk without any known benefit. However, some members of the BAC observed that a certain level of risk is inevitable in research involving human subjects. So long as research participants have been informed and voluntarily agree to assume such risk, then they should be allowed to participate in the research. But even by this approach, it was questionable if difficult issues (in this case, risk assessment) should be left to IRBs. Some BAC members were concerned that IRB members who have not been trained in medicine or science would not be able to properly appreciate the medical risk entailed. However, other members pointed out that ethical deliberation include more than risk assessment, although the latter is undoubtedly an important consideration.

Between end August to early October 2007, a separate consultation paper on egg donation for research was drafted. The draft ED Consultation Paper comprises six main parts: (1) an introduction of the issues, (2) a description of the use of human eggs in research, and especially

in somatic cell nuclear transfer technology, (3) a description of the sources of human eggs, (4) an analysis of the procedures and risks involved in egg donation, (5) a description of the legal and regulatory framework, and (6) a specific treatment of the issue of payment for providing eggs for research. The format of the draft was crafted by the Secretariat with the HECR Working Group and the PES to set out the costs and benefits with different policy options and to invite public feedback on what would be considered to be an acceptable balance. For instance, an issue presented to the public was whether it would be ethically proper to pay a woman for donating eggs to research in the context of potential downside risks. These risks are explained as adverse health consequences to donors and exploitation of women (especially through financial inducement of poor women) in various forms. Should a payment or compensation scheme be allowed, the transnational reach of financial inducement was explicitly indicated as a source of concern, in view of the fact that many foreign women take up low-wage work in Singapore.

The appropriateness in the use of a particular classificatory term such as 'entity' as collective reference to an IVF embryo, a parthenote, and similar 'artifacts' was based on opinions of medical and scientific experts. More importantly, the BAC has strongly relied on medical and scientific opinions in the assessment and articulation of scientific viability and risk. I provide two illustrations. First, the relative effectiveness of 'fresh' as opposed to 'immature' eggs was based on scientific judgment. In the draft ED Consultation Paper, the replacement of the word 'ineffective' in the third line of the following paragraph with 'less effective' was based on medical and scientific opinions obtained:[654]

[654] Draft ED Consultation Paper, Fieldnotes, 27 September 2007, at paragraph 16 (Emphasis added).

> In SCNT research, fresh eggs or surplus eggs from women undergoing fertility treatment are preferred to immature eggs or eggs that have failed to fertilize after IVF. Eggs that have failed to fertilize after IVF are *ineffective* as they have been shown to have limited developmental potential and the resulting embryos contained chromosomal abnormalities.

Second, the risk entailed in egg donation was also a matter determined based on existing medical and scientific knowledge. The original Paragraph 23 of the draft ED Consultation Paper explicitly highlighted the possible risk connected to hormonal stimulation for the purposes of egg donation:[655]

> There is also a concern that ovarian stimulation may lead to an increased risk of future infertility and cancers of the breast, ovary and uterus. However, there is no scientific evidence to support this. More research is required to determine if there are definite undesirable long-term effects of ovarian stimulation.

A milder language was subsequently adopted to de-emphasize potential risk from egg donation as the claim lacks scientific backing. The last sentence of the paragraph was deleted, and hence revised as:[656]

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655 *Ibid*, paragraph 23.

656 Draft ED Consultation Paper, Fieldnotes, 27 September 2007.

> While there is also a concern that ovarian stimulation may lead to an increased risk of future infertility and cancers of the breast, ovary and uterus, there is however no scientific evidence to support this.

There was discussion at the Working Group level as to whether this potential risk should be stated in the ED Consultation Paper at all. Legal considerations were taken into account in the ultimate decision to retain much of Paragraph 23. The Working Group was influenced by recent legal developments in medical jurisprudence that gave increasing significance to patient autonomy in decision-making. The fact that research was not expected to confer any immediate benefit on research participants was a stronger justification for providing all relevant information, including information not regarded to be scientifically certain, to the participant. Some degree of agreement over expected level of risk enabled the consolidation of the issues and discussions in the ED Consultation Paper, especially after various meeting between September and October 2007. The objectives of an early draft of the ED Consultation Paper were vaguely stated. By November 2007, these were subsequently systematized as a set of structured questions.

Early discussions on the provision of some form of payment for egg donation revolved around concerns over inducement and the commoditization of the body. If payment is to be allowed, there was a sense that a regulatory body should be established or designated to ensure that there is no inducement in the procurement of eggs for research. Also recognized were the possible ramifications on organ donation on the one hand, and small-sample tissue donation on the other. It is further critical to note that the BAC was not operating within a normative vacuum.

Biomedical ethics has a strong stance against the commodification of the body. Hence in medical practice, financial compensation for the provision of organs has remained controversial. In a research setting, the BAC's position expressed in the report on 'Human Tissue Research' is: the giving of tissue for research should be altruistic although reasonable compensation for certain expenses (such as for travel) is permitted.[657]

Three possible policy approaches to financial compensation of women providing eggs for research are developed based on international discourses on the subject, as well as the regulatory approaches of other jurisdictions. They are set out in the ED Consultation Paper as:[658] (a) No compensation but only reimbursement of expenses incurred; (b) Reasonable compensation for time, risk and inconvenience, in addition to reimbursement of incurred expenses; and (c) Substantial compensation that amounts to outright payment of eggs as a commodity.

The ruling out of option (c) was relatively straightforward for the BAC as there are legal precedents going back several decades that block any donor's proprietary interest in subsequently derived cell lines. It also noted a relatively universal agreement, especially so in research institutions, that the donor relinquishes all rights to the donated materials at the point of donation. However, the BAC considers it expedient for this to be made explicitly clear to donors. A practical rationale for this limitation is that it would be extremely difficult to apportion the value of the genotype of the cells towards the final product as compared to all the information that researchers would gather and apply to the research.

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657 Bioethics Advisory Committee, *Human Tissue Research.* Singapore: Bioethics Advisory Committee, 2002, at paragraph 8.6, which states: "Although the donor may make an outright gift of his or her tissue in the sense that she renounces any property rights to or in connection with the tissue, it is entirely open to the donor to stipulate or define the kind of research uses to which the tissue may be applied."

658 Paragraph 39 of the ED Consultation Paper, at A-14. These approaches are reiterated in Paragraph 4.26 of the ED Report, at 21-22.

During a key meeting of the BAC on the issue of compensation, it felt that compensation (if allowed under options (a) and (b)) should be proportionate, although the difficulty in preventing inducement in every situation was acknowledged.[659] Compensation could range from taxi fare, hospital charges to loss of time from work. There would quite possibly be very uneven distribution for compensating loss of time from work, although it might be possible to avoid inducement from a theoretical standpoint, since a donor would not receive more than what she would otherwise gain from working, in contrast to providing a standard compensation, which might be an inducement for very poor women. On the practicality of providing compensation based on earnings, a BAC member pointed out that compensation based on tax returns, for National Servicemen called up for military training, represented such a scheme. It was further noted that a large sum of money is paid by pharmaceutical companies or clinical research companies to healthy volunteers in Singapore for participating in Phase I drug trials. The justification that was presented for the large payment was compensation for the risk of exposing a person to a novel drug. Compensation for egg donation would be analogous to compensation for participation in phase 1 of clinical drug trials. For the purposes of the ED Consultation Paper, it was decided that the BAC could recommend that compensation be provided for time, risk and inconvenience, and that the level of compensation should not be such that it amounts to an unreasonable inducement.

A difficulty that I was confronted with in working on the ED Consultation Paper was achieving a sufficiently clear understanding of the extent of the risks posed to donors, and especially the risk of OHSS. Grappling further with the issue, I discovered a very deep institutional knowledge of risks that has been developed, again mainly by institutions in the US. The documents of the NRC

[659] Fieldnotes, 13 August 2008.

and the IOM have been important because of the close research and policy relations that BAC members shared with colleagues in the US, as well as the recognition that it is the 'best scientific knowledge of the day' on health risks relating to egg donation. This display of 'trust' was a pragmatic choice, as the BAC shared the NRC's position on the standards of good analysis,[660] and did not see the need to 're-invent the wheel' by examining the scientific and medical bases and perimeters. However, the NRC did also indicate that even for good qualitative analysis, one should be mindful that procedures tend not to be clear-cut, the difficulties in validating findings, and that "technical adequacy is a necessary but not sufficient characteristic: analysis must also be relevant to the given risk decision."[661] In the end, these ambiguities did not appear to have a significant impact as the subject matter and target audiences were essentially self-selecting so that the criteria of effectiveness were broadly satisfied. The 'correct' scientific experts were consulted, and the 'correct' scientific sources were applied. For the public, the documents of the BAC communicated accurate information and balanced discussions.[662] In the section that follows, we consider the genealogy of a technical conception of risk that was adopted by the BAC.

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660 The NRC has set out several characteristic features of good quantitative analysis. National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*. Washington D.C.: National Academy Press, 1996, at 100-102.

661 *Ibid*, at 101.

662 *Ibid*, at 152. The criteria have been identified as: (1) getting the science right; (2) getting the right science; (3) getting the right participation; (4) getting the participation right; and (5) developing accurate, balanced and informative synthesis.

5.3 Genealogy of Institutionalized Risk

Heather Douglas explains that in the 1970's, a shift in policy stance away from absolute safety in regulatory efforts led to a focus on risk analysis for the determination of risk significance.[663] Fresh uncertainties were introduced into what was considered to be settled science (or 'trans-science', where uncertainties gained prominence and importance). Risk analysis itself is regarded as comprising two distinct parts: risk assessment (where scientific knowledge is relied upon to provide insights on the extent and nature of the risk), and risk management (where determinations are made as to how risk is to be handled in practice). The origins of the risk assessment/risk management distinction was in turn traced to William Lowrance, who according to Douglas wanted to keep the more 'objective' basis of risk assessment from essentially value-based risk management.[664] Douglas considers as advantageous this conceptual insulation of the more science-based part of risk analysis as risk assessment "*should be* protected from pressures to shift the assessment of risk because the results are politically inconvenient".[665] This is further important in securing scientific integrity, and in summarily setting out current scientific understanding of the risk concerned.[666] Iain Wilkinson makes a similar argument that: "… 'objectivity' is a social value and what we accept as 'objective' knowledge about our world is always shaped by the quality of our social commitments and cultural worldviews."[667]

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663 Heather E. Douglas. *Science, Policy, and the Value-Free Ideal*. Pittsburg: University of Pittsburg Press, 2009.

664 Lowrance attributed four steps to measuring or 'assessing' risks. See William W. Lowrance. *Of Acceptable Risk: Science and the Determination of Safety*. Los Altos: W Kaufmann, 1976, at 18; cited by Heather Douglas: *Ibid*, at 140. Douglas indicates that "by separating "measuring/assessing risk" from "judging safety," Lowrance intended to separate the scientific component of the process – measuring the risk – from the value-laden social and political component of the process – deciding what to do about the risk": *Ibid*.

665 *Ibid*, at 141 (Emphasis in original).

666 Heather Douglas adds: "one reason for making a distinction between the two phases was to defend the integrity of the first phase, risk assessment, so that science could be protected from political pressure". *Ibid*, at 144.

667 Iain Wilkinson, *Risk, Vulnerability and Everyday Life*. London and New York: Routledge, 2010, at 57.

This risk assessment-risk management distinction has been formally endorsed in a report (called the 'Red Book') of the NRC on risk management by federal agencies. Primarily focused on risk to health presented by toxic substances such as asbestos, risk assessment was taken to be concerned with the characterization of the potential adverse health effects of human exposures to environmental hazards.[668] To this effect, four major steps are encompassed in the assessment: hazard identification, dose-response assessment, exposure assessment and risk characterization.[669] In contrast, risk management is conceptualized as a decision-making process involving the weighing of policy alternatives and selecting the most appropriate regulatory action, in that the results of risk assessment are integrated with (engineering) data, as well as with social, economic and political concerns.[670] Acknowledging that there will inevitably be gaps in scientific knowledge and other limitations (such as limited analytical resources and analytical complexity), a recommendation in the Red Book was for uniform inference guidelines to be developed to ensure that risk assessments are consistently applied by federal agencies and protected from inappropriate policy influences.[671] The Committee considered such guidelines to be feasible although the degree of flexibility and legal authority among different sets of guidelines may differ. Such guidelines are further desirable as they "provide a systematic way to meet statutory requirements, to inform the public and regulated industries of agency policies, to stimulate public comment on those policies, to avoid arguing generic questions anew in each specific case, and to foster consistency and continuity of approach".[672] As Douglas observes, the NRC attempts to secure scientific integrity by ensuring that specific economic and social

668 Committee on the Institutional Means for Assessment of Risk to Public Health, Commission on Life Sciences, National Research Council. *Risk Assessment in the Federal Government: Managing the Process*. Washington DC: National Academy Press, 1983, at 18.
669 *Ibid*, at 19-20.
670 *Ibid*, at 3.
671 *Ibid*, at 7-8.
672 *Ibid*, at 4.

considerations do not have undue influence, even though the risk assessment process is not completely scientific.[673]

This essentially technical approach to risk assessment broadly reflects popular understanding of risk as a calculative reasoning, often applied in the evaluation of acquisitive opportunities. For many, risk has negative connotations.[674] Weber has famously traced the origins of the economic life of modernity in Western Europe by relating a form of calculative reasoning embedded in everyday (religious) routines, to a 'formal rationality' that enables the efficient ordering and resolution of problems through technical rules and procedures in structures of economy, society and state.[675] To satisfy a psychological need to organize the world around an "imperative of consistency", human beings have relied on this calculative rationality to mediate between their ideal expectations and the brute facts of experience.[676] An institutionalized form of rationality in pre-modernity is religion, which has attempted to provide meaning to all aspects of life and to provide practical solutions to pain and suffering.

In explicating the institutional basis of risks, Mary Douglas and Aaron Wildavsky point to two other important aspects of risk. First, they observe that pollution ideas are an instrument of control.[677] This idea could be further developed by relating it to Foucauldian notion of the relationship between power and subjectivity. In studying the impact of 'power relations' on the

673 Heather E. Douglas. *Science, Policy, and the Value-Free Ideal*. Pittsburg: University of Pittsburg Press, 2009, at 143.

674 Peter L. Bernstein. *Against the Gods: The Remarkable Story of Risk*. New York: John Wiley & Sons, 1998.

675 Max Weber, *The Protestant Ethic and the Spirit of Capitalism*. New York and London: Routledge, 2005.

676 Max Weber, Religious rejections of the world and their directions. In H.H. Gerth and C.W. Mills (eds), *From Max Weber*. London: Routledge, 1948, at 324.

677 Mary Douglas and Aaron Wildavsky, *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers*. University of California Press: Berkeley and Los Angeles, 1982, at 47. It was noted that when central establishment is strong, it holds the monopoly of explaining the natural order. Its explanations of misfortune make social outcasts carry the stigma of vice and disease.

'field of possibilities', Foucault shows how the assumption by individuals and groups of particular behaviors as preferred way of living corresponds with a governmentality that structures the possibilities of action.[678] Here, the language of risk is a primary technique of governance, where risk discourse structures subjectivity and social relations, essentially by directing conduct along a designated course of action and towards particular goals. Building on this idea, Mitchell Dean argues that there is no such thing as risk in reality. Perhaps reflecting a degree of Weberian sensibility, risk is regarded as no more than a means of ordering reality and rendering it into a calculable form.[679] Others have observed a neoliberal agenda in the language of risk as deployed in some manner of governance.[680] The subject of governmentality is discussed in Chapter 6.

The second aspect of risk that Douglas and Wildavsky explicate is positionality. Drawing on the theory of bounded rationality and prospect theory,[681] they observe that in risk perception, humans act less as individuals and more as social beings who have internalized social pressures and delegated their decision-making processes to institutions. They attempt to manage by following social rules on what to ignore when faced with unknown risk: institutions are their problem-simplifying devices.[682] Knowledge of danger is necessarily partial and limited, as the kind of guesses about natural experience depends very largely on the kinds of moral

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678 Michel Foucault, The subject and power. In Hubert Dreyfus and Paul Rabinow (eds), *Michel Foucault: Beyond Structuralism and Hermeneutics*. Chicago: Chicago University Press, 1982, pp 208-226, at 220-221.

679 Mitchell Dean, Risk calculable and incalculable. In Deborah Lupton (ed), *Risk and Sociocultural Theory: New Directions and Perspectives*. Cambridge: Cambridge University Press, 1999, pp 131-159, at 131-2.

680 Hazel Kemshall, *Risk, Social Policy and Welfare*. Buckingham: Open University Press, 2002. See also Nikolas Rose, *Powers of Freedom: Reframing Political Thought*. Cambridge: Cambridge University Press, 1999.

681 Prospect theory contradicts a generalization in decision theory that people are generally risk adverse. They show that people are not risk averse for negative prospects, only positive ones. See Mary Douglas and Aaron Wildavsky, *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers*. University of California Press: Berkeley and Los Angeles, 1982, at 77-78.

682 Douglas and Wildavksy seem to suggest that there is no intermediate ground between objectivity and subjectivity. *Ibid*, at 80.

education of the people doing the guessing. In contrast to formalistic methods of risk assessments, rational human behavior does not use elaborate calculations for making crisis decisions nor do they separate out risks one by one. However, the inability to systematize and rationalize all aspects of social life has contributed to more intense encounters with the 'irrationalities' in life, such as suffering and evil. Building on Weberian analysis, Iain Wilkinson argues that distinct cultures of moral argument, juridical process and political response (with their own tradition of symbolic representation and established patterns of social disclosure and response) shape the courses of rationalization taken up under the effort to restore order to the world in response to particular instances of catastrophe and human tragedy.[683] This argument has found some support from developments in the life sciences. An effect of quantifying some aspects of uncertainty under the technical rubric of 'risk assessment' for the purposes of 'risk management' is to bring to light other aspects that are unquantifiable. Those aspects that could be assessed and managed have generally been regarded as scientific or medical risks, whereas those that could not were treated as 'ethical' or 'moral' concerns.

The limitations of technical risk assessment did not elude the attention of policy-makers and their expert advisors. In a subsequent report, the NRC highlighted that risks should be understood relationally, especially between producers and users of scientific information on risks and the ways in which such information is communicated.[684] This communicative aspect of risks was elaborated on by the Presidential/Congressional Commission on Risk Assessment and Risk

683 Iain Wilkinson, *Risk, Vulnerability and Everyday Life*. London and New York: Routledge, 2010, at 31-32. Iain Wilkinson echos Weber's concern that even with more refined rationalization in scientific technical analysis, there will be no guidance in fundamental human concerns relating to the meaning and purpose of life. See Max Weber, Science as a vocation. In H.H. Gerth and C.W. Mills (eds), *From Max Weber*. London: Routledge, 1948.

684 Committee on Risk Perception and Communication, National Research Council. *Improving Risk Communication*. Washington, D.C.: National Academy Press, 1989, at x.

Management. Taking up a topic identified as a research need in the NRC's 1989 report,[685] the US NRC elucidated on 'risk characterization' as a means by which it could be improved to better inform decision-making and resolution of controversies over risk, in its 1996 report.[686] It argues that risk characterization should be a decision-driven activity directed at informing choices and solving problems, and not an activity added at the end of risk analysis.[687] Reflecting on its earlier conceptualization of risk, the NRC considered that risk characterization should not only be a representation of existing scientific knowledge.[688] Aside from being decision driven, the process by which risk is characterized should recognize all significant concerns, reflect both analysis and deliberation, drawing on feedback from interested and affected parties, and be appropriate to the decision.[689] Under this expanded framework, the NRC sets out a new definition of "risk characterization" as "a synthesis and summary of information about a potentially hazardous situation that addresses the needs and interests of decision makers and of interested and affected parties. Risk characterization is a prelude to decision making and depends on an iterative, analytic-deliberative process".[690] Within this framework, risk decision making could be undertaken through a set of diagnostic steps.[691]

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685 *Ibid*, at 13. The other eight research topics have been identified as risk comparison, role of message intermediaries, pertinency and sufficiency of risk information, psychological stress, the 'mental models' of recipients, risk literacy, retrospective case studies of risk communication and contemporaneous assessment of risk management and risk communication.

686 National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*. Washington D.C.: National Academy Press, 1996, at xi.

687 *Ibid*, at 2. Risk characterization as defined in the 1983 report suggests that it is the final step in the process of risk assessment. Commission on the Institutional Means for the Assessment of Risks to Public Health, Commission on Life Sciences, and National Research Council, *Risk Assessment in the Federal Government: Managing the Process*. Washington D.C.: National Academy Press, 1983, at 20.

688 National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*. Washington D.C.: National Academy Press, 1996, at 32.

689 *Ibid*, at 16. Analysis is considered as using "rigorous, replicable methods, evaluated under the agreed protocols of an expert community – such as those of disciplines in the natural, social, or decision sciences, as well as mathematics, logic, and law – to arrive at answers to factual questions" (at 3-4), whereas deliberation is "any formal or informal process for communication and collective consideration of issues" (at 4).

690 *Ibid*, at 27.

691 *Ibid*, at 142-149.

Although risk analysis could be a means by which one (especially an expert) could be seen as hiding his or her subjective preferences behind technical jargon and complexity in order to influence individuals, win an argument or push one's agenda, effective risk communication is a critical means by which level of understand can be raised for the purposes of making informed choices. The division between the two has more often than not been difficult to distinguish clearly. A number of difficulties in communicating risks have been highlighted as including: (1) absence of a single overriding problem that can be simply communicated; (2) people do not all share common interests and values, hence expectations may differ greatly from one person to another; (3) values, preferences and information needs may not be determined easily; (4) risk management decisions do not affect everyone uniformly as some citizens may be harmed but other benefit; and (5) experts may not agree on scientific assessment of risks.[692] Two other crucial sources of problems in risk communication have been identified as those deriving from institutional and political systems, and those from risk communicators and recipients. The former – defined by legal considerations, sources of (and fragmented) authority that includes formal (such as the state) and informal (such as peer pressure) ones, and systematic biases – tends to be more difficult to address than the latter. The latter is in turn focused on "establishing and recognizing credibility, making the messages understandable, preparing messages in an emergency, capturing and focusing attention, and getting information".[693]

The challenges in 'risk communication' reflect the difficulties posed by uncertainties that remain unquantifiable. A direct impact of attempting to address such uncertainties by duly 'informing'

[692] Committee on Risk Perception and Communication, National Research Council. *Improving Risk Communication*. Washington, DC: National Academy Press, 1989, at 3-4.

[693] *Ibid*, at 6.

the public provides the basis for Ulrich Beck's notion of 'risk society', which could be read as a heightened awareness of risk, and particularly its ubiquity. Beck argues that social classes have given way to individualization as the implications of society now filter down to every person. Using the Chernobyl incident as a key epistemic event, he argues that risks generated by industrial society affects everyone. However, the extent of exposure differs so that risk becomes a force that shapes relations rather than capital (or forces of production). Hence, risk is the 'reflexive modernization' that is re-shaping the relationship between politics and science.[694] Unlike social phenomena like poverty, many types of risk are perceivable only through the intermediation of science. In that way, scientific knowledge constitutes 'persons' by risk profile,[695] but the process itself is abstract and lacks experiential basis. Hence the complexity and uncertainty in scientific causal analysis are often not sufficiently appreciated by the public, whereas science is more commonly understood as means of control and prediction. Disasters like Chernobyl heightens public awareness of the inability of science to control and predict, and thereby undermines the credibility of scientific expertise. In addition, science as itself a producer of risk has often been only able to perceive the risk retrospectively.[696] Increased knowledge of risks creates its own sociality but not in the conventional sense of social classes.[697] Instead, Beck considers this sociality to nurture the *cosmopolitanization* of an individual, this being a multidimensional process and involves "the formation of multiple loyalties, the spread of transnational lifestyles, the rise of non-state political actors…and the development of a different

694 Ulrich Beck. *Risk Society: Towards a New Modernity*. London: Sage Publications, 1992, at 36.
695 *Ibid*, at 59.
696 *Ibid*.
697 *Ibid*, at 47 and 88.

(cosmopolitan) globalization involving worldwide recognition of human rights, worker's rights, global protection of the environment, an end to poverty and so on."[698]

Like Ulrich Beck, Anthony Giddens regards late modernity as a 'risk culture', characterized by institutional and individual reflexivity that attempt to cope with the expansion of disembedding mechanisms, especially in the forms of expert knowledge and globalization.[699] Greater knowledge has contributed to greater uncertainty, as well as an awareness that expert knowledges are contingent and subject to revision.[700] More importantly, expert knowledges have become critical resources in construction of the self, which is seen as malleable and a reflective responsibility to be assumed in taking charge of one's life trajectory.[701] Threats are conceptualized as 'risks' rather than as a 'given', and can be subject to "an essential calculus" to promote certainty and order. Where risk cannot be precisely calculated, the uncertainty could be further managed through the development of various 'scenarios' of risk with different degrees of plausibility.[702] Unlike Beck, Giddens argues that trust continues to be necessary, as 'acceptable' risk is central to sustaining trust and vital to establishing ontological security, or "the confidence that most human beings have in the continuity of their self-identity and in the constancy of the surrounding social and material environments of actions." Without this trust, one would be engulfed by feelings of anxiety and dread, and paralyzed by inaction from indeterminacy.[703]

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698 Ulrich Beck. Cosmopolitan realism: on the distinction between cosmopolitanism in philosophy and the social science, *Global Networks* (2004) 4, 2: 131-156, at 136.

699 Anthony Giddens, *Modernity and Self-Identity: Self and Society in the Late Modern Age*. Cambridge: Polity Press, 1991, at 3 and 21.

700 *Ibid*, at 20.

701 *Ibid*, at 32-33. Giddens observes (at 7) that the body is seen less as a 'given' but as subject to individual manipulation and will.

702 Ulrich Beck, Anthony Giddens and Scott Lash. ***Reflexive modernization : politics, tradition, and aesthetics in the modern social order***. Cambridge: Polity Press, 1994, at 186.

703 Anthony Giddens, *The Consequences of Modernity*. Stanford: Stanford University Press, 1990, at 35 and 92.

Hence, whereas Beck considers a critique of expertise to be reflexivity, Giddens argues that reflexivity arises from trust in expertise.

An upshot of the lengthy discussion so far is to highlight the incremental development of an institutional risk discourse and communication. As we have noted, Foucauldian tradition makes clear that discourses establish social norms and realities, and could themselves be the basis of sociality. More importantly for us, this discursive development as various forms of institutional learning took place over three decades, and it ultimately culminated (perhaps a little overstated here, but well worth the emphasis) in a workshop report by the IOM (which is part of the NRC) on medical risks in egg donation. This was one of the most important documents to be considered by the BAC in preparing the ED Consultation Paper and subsequently the ED Report.[704] This report was brought to the attention of the BAC by a member of its International Panel of Expert, Professor Bernard Lo, who was the co-chair of the Scientific and Medical Accountability Standards Working Group of the CIRM, which develops guidelines for stem cell research in California. Aware of the risks that oocyte donation could present, the CIRM contracted with the National Academies to organize a workshop to gather expert opinion on "what is known about these risks, what needs to be known, and what can be done to minimize them".[705] The report provides a summary of the views expressed by participants at the workshop held in San Francisco on September 28, 2006.

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[704] Institute of Medicine and National Research Council, Linda Giudice, Eileen Santa and Robert Pool (eds). *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research*. Washington D.C.: National Academies Press, 2007.

[705] *Ibid*, at 1.

Two different categories of potential risks were identified by the workshop participants: 'acute risks' and 'long-term risks'. The first category of 'acute risks' comprises three sub-categories that are linked to the different stages of the oocyte retrieval process. The risk of OHSS is an 'acute risk' that could arise from a regime of hormone shots administered to donors to increase the number of eggs that can be retrieved. The symptoms to OHSS include increased ovarian size, nausea and vomiting, accumulation of fluid in the abdomen, breathing difficulties, hemoconcentration and, in the most severe cases, blood clots or kidney failure. It was generally felt that the risk of OHSS for egg donors is lower than for women involved in IVF as a large percentage of the severe complications of OHSS are linked to hormonal changes from accompanying pregnancy. While it is not possible to fully eliminate the risk of OHSS, it could be minimized through a number of precautionary practices including the modification of the hormone treatment regimen to minimize the factors that contributes to hyperstimulation (such as higher than normal egg follicle count) and the exclusion of certain donors, such as those with irregular menstrual cycles, ovaries with polycystic appearance and possibly those with high levels of androgens.[706]

The other two sub-categories of 'acute risks' are associated with surgical procedure, including anesthesia, and psychological disturbances that could include anxiety, mood swings and post-donation adjustments.[707] Surgery is required to retrieve the eggs from the follicles upon the completion of hormone treatment. A needle is used, penetrating through the vagina and into the ovary, to aspirate individual follicles in the retrieval process. There is very small risk of vaginal bleeding, intestinal injuries and peritonitis, and only 2 in every 100,000 cases had complications

[706] *Ibid*, at 2 and 17-22.
[707] *Ibid*, at 11.

that required surgery to correct.[708] Complications due to infection and ovarian torsion were also found to be of very low risk. A number of factors could increase the risk of adverse occurrences associated with surgery, but they were considered to be more prevalent among IVF patients than healthy oocyte donors.[709] Risks from anesthesia were also found to be low as egg donors are unlikely to share certain high-risk factors.[710] As for psychological disturbances, a categorical analysis was similarly applied, where psychological risk was associated with the screening process, problems surrounding the donation procedure itself, and post-donation adjustment to the donation.[711] These risks could be ameliorated through better selection process and through more effective counseling.

The second category of potential risks is longer-term, and relate to the development of breast, ovarian and endometrial cancers, as well as concerns over its impact on future fertility.[712] An expert (Dr Roberta Ness) indicated that there is some data to suggest that intensive and regular use of fertility drugs could cause an increase in the risk of breast, ovarian and especially endometrial cancers. Studies have been inconclusive as they did not follow their subjects for sufficient durations of time.[713] More research was considered to be necessary to examine the long-term impact that fertility drugs may have on breast and ovarian cancer prevalence rates. For uterine cancer, the possibility of an increased risk from the use of fertility drugs was recognized even though available data did not have statistical significance.[714] As for the impact of fertility

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708 *Ibid*, at 38-39.
709 *Ibid*, at 39; such factors include previous surgeries, a history of pelvic inflammatory disease, endometriosis, and pelvic adhesions.
710 *Ibid*; such factors were indicated as being male, older, obese or having surgery in an emergency setting.
711 *Ibid*, at 48.
712 *Ibid*, at 11.
713 *Ibid*, at 26.
714 *Ibid*, at 29.

drugs on a woman's long-term fertility, this concern was considered to be scientifically unfounded as no evidence was found to support such a claim.[715]

As a matter of risk communication, it is interesting to note that the experts have cautioned against an unreflective reliance on probabilities. This passage from the report is instructive on the notion of risk as interpreted vis-à-vis a particular type of risk subject:[716] "Nearly all of the speakers cautioned against relying on probabilities because the most important strategy in collecting oocytes for stem cell research is to be cautious in relying on probabilities, because the most important strategy to minimize the potential risks to oocyte donors is to make decisions based on *common sense on a case-by-case basis*. Of course, physicians try not to subject any of their patients to unnecessary risks, but because research donors represent a special situation – women who are undergoing a procedure not for their own benefit but for the benefit of others – the workshop participants said that *even greater care* should be taken to make sure that these donors do not pay for their altruism with their own health."

This epistemic history of risk assessment, management and communication has been critical to the way that the BAC has categorized the types of donors, and the ethical considerations and requirements that attend to each category. In addition, the BAC has adopted similar proposals to minimize the risk of OHSS and to encourage alternative sources of oocytes to be considered, such as the use of immature eggs (that could be matured in vitro), deriving eggs from polycystic-appearing ovaries, and retrieving eggs from cadavers.[717] Neither ED Consultation Paper nor the ED Report set out the technical information in great depth but relied on referencing and

715 *Ibid*, at 30.
716 *Ibid*, at 54 (Emphasis Added).
717 *Ibid*, at 60.

appending such information. Instead, with the benefit of a somewhat pre-fabricated framework for risk assessment and management, the BAC was able to focus on the definition of 'ethical' risks. As we will recall from our discussion above, such risks relate to uncertainties that could not be quantified within existing knowledge systems.

To briefly summarize, the approach of the NRC and its related bodies (particularly the NAS and the IOM) in studying the link between risk science and policy has been to focus on specific aspects of risk. As we have seen, it has earlier on called for a clear distinction to be made between risk assessment and risk management in its 'Red Book'. Subsequent reports have addressed the responsiveness of risk assessment, communicability of risks and how risks could be understood through different means of characterization. More recent studies have focused on risks generated through specific scientific practices or usage. Other policy bodies have preferred a broader 'framework-like' approach. While acknowledging the usefulness of risk assessment as an analytical process, the Presidential/Congressional Commission explained that this process "was developed because Congress, regulators, and the public require scientists to go beyond scientific observations of the relationships between exposures to chemicals and pollutants and their effects on people, the environment, or test systems [ie risk factors], and to rely on many scientific inferences and assumptions to answer social questions about what is unsafe".[718] While public expectation might not be simply altered, the Commission considered it more feasible for analysts to provide more explicit descriptions of the "assumptions, data sources, sources of uncertainty, and distribution of benefits and costs across society associated with economic

[718] The Presidential/Congressional Commission on Risk Assessment and Risk Management. *Risk Assessment and Risk Management in Regulatory Decision-Making*. Washington DC: The Presidential/Congressional Commission on Risk Assessment and Risk Management, Final Report, Vol. 2, 1997, at iii.

analyses, in parallel with the descriptions associated with risk assessments."[719] The Commission further perceived a need to re-calibrate regulatory focus from micro-assessment of risk to the overall goal of sustainable development through risk reduction and improved health status.[720] Under its proposed Risk Management Framework, it would be necessary to conceptualize a potential or current problem in the broader context of public or environmental health in order to manage risks more effectively and efficiently.[721]

More recently, the International Risk Governance Council (IRGC) – a private, independent, not-for-profit Foundation based in Geneva – published a White Paper on an integrated, holistic and structured approach (or framework) to risk governance.[722] As with other policy-based conceptualization of risks, the risk governance framework proposed by the IRGC has, as its 'generic elements', risk assessment, risk management and risk communication. Unlike other relatively mechanistic approaches to risk management however, the IRGC attempts to include societal context to its framework, but taking into account risk perception, interaction among different actors, policy-making and regulatory style, and socio-political impacts. By contextualizing the generic elements of risk governance, the IRGC puts forward a risk process as a conceptual tool, or "risk handling chain".[723] A key outcome of this risk process is a system of characterization as simple, complexity-induced, uncertainty-induced or ambiguity-induced. Categorization can then enable the selection and implementation of an appropriate management strategy, ranging from routine-based risk reduction considerations and practices, to measures that

719 *Ibid*, at iv.
720 *Ibid*, at i-ii.
721 *Ibid*, at ii to iii.
722 International Risk Governance Council. *Risk Governance: Towards an Integrative Approach*. Geneva: International Risk Governance Council, September 2005, at 5.
723 *Ibid*, at 12.

enable systemic risk absorption and conflict resolution.[724] Risk communication is treated separately as being cyclical in character (like a feedback loop) and recognized as a companion to all four phases of addressing and handling risk.[725] Underlying the framework of risk process and communication are three major value-based premises and assumptions, these being the inclusion of both the 'factual' and the 'socio-cultural' dimension of risk, emphasis on inclusiveness as a critical aspect of the governance process, and implementation of the principles of 'good' governance.[726] Further helpful in its analysis is the recognition that the nature of risk management also depends on regulatory regimes or governmental styles (or, more generally, political culture). The IRGC observes:[727] "Risk management depends, however, not only on scientific input. It rather rests on three components: systematic knowledge, legally prescribed procedures and social values…"

The BAC did not perceive the need (or perhaps even the liberty) to query an already well-established framework in relation to quantifiable risks associated with egg donation. Its gravitational force is to a large degree grounded relationally to various expert communities and to the perception or reputation of doing 'good science'. In this respect, Deborah Lupton seems right to criticize the representations of modernity by Beck and Giddens as being too simplistic for the failure to acknowledge the complexity of responses to expert knowledge. They are also too speculative about structural and organizational processes without sufficient acknowledgement of "the communal, aesthetic and shared symbolic aspects of risk in their focus

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724 *Ibid*, at 15-16.

725 Key topics to be addressed in risk communication have been set out by the IRGC, having taken into account major functions of risk communication. *Ibid*, at 54-57.

726 *Ibid*, at 12. The principles of 'good governance' include "transparency, effectiveness and efficiency, accountability, strategic focus, sustainability, equity and fairness, respect for the rule of law and the need for the chosen solution to be politically and legally realisable as well as ethically and publicly acceptable".

727 *Ibid*, at 62.

on individualization."[728] Rather than perceiving risk as 'out there' and directive, Mary Douglas and Aaron Wildavsky have argued that risk is, or otherwise relates to, the 'other' against which blame could be attributed in order to strengthen group unity. Hence even in the face of seemingly ever present risks of human violence, risks from technology or from economic failure, the manner in which they are identified and addressed is never straightforward but settled by a preference among different kinds of favored social institutions.[729] They indicated that risk could be deployed to maintain unity in the face of eroding group solidarity. Plausibility depends on enough people wanting to believe in the theory, and this depends on enough people being committed to whatever moral principle it protects.[730] Hence, "[p]ollution ideas cluster thickest where cherished values conflict".[731] Even then, unquantifiable risks that fall outside the purview of expert knowledge remain. The BAC recognized the potential long term health risks that the egg donation could pose, aside from moral concerns over the commodification and commercialization of the human body and with exploitation. These then became the primary concerns of the ED Consultation Paper and the public consultation.

5.4 Public Consultation on Egg Donation

During the public consultation, the ED consultation paper was sent to 94 research, governmental and healthcare institutions (including 21 fertility clinics) and professional and religious

728 Deborah Lupton, *Risk*. London and New York: Routledge, 1999, at 82. See also John Tulloch and Deborah Lupton. *Risk and Everyday Life*. London, Thousand Oaks and New Delhi: Sage, 2003.

729 Mary Douglas and Aaron Wildavsky, *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers*. University of California Press: Berkeley and Los Angeles, 1982, at 81 and 187.

730 *Ibid*, at 38.

731 *Ibid*, at 43.

organizations for comment. Members of the public could download a copy of the consultation paper through the BAC's website, and feedback could also be provided through various means including email, an online discussion forum and an e-consultation platform (through a public outreach system called 'REACH'). Feedback from the discussion forum and e-consultation platform was provided by way of responses to questions set out in the context of a factual scenario and in the format below.[732]

[732] The scenario, as well as a summary of responses from REACH Online Discussion Forum and e-Consultation, is set out in the ED Report (at pp. D-1 to D-3), although the overall format is reproduced here for completeness.

Public Consultation on Donation of Human Eggs for Research

The Bioethics Advisory Committee (BAC) has recently released a Consultation Paper on the donation of human eggs for research. [link provided] The Paper raises issues related to the provision of human eggs for research, especially research involving embryonic stem cells. The BAC seeks views from the public on:

- whether healthy women, not undergoing fertility treatment should be allowed to donate eggs for research and if so, under what conditions; and
- whether compensation of egg donors amounts to inducement.

You are also invited to attend a public talk on this topic on 22 November 2007. The details are available on the BAC website: www.bioethics-singapore.org

You may contribute to the Consultation by:

a. Providing us your views on the scenario below or any issues in the Consultation Paper by sending an email to contactus@bioethics-singapore.org or by post to:

11 Biopolis Way
#10-12 Helios
Singapore 138667

b. Setting up a group or using an existing group that meets regularly for a related or unrelated purpose, to discuss these issues. Where there is a significant number of people meeting, and if it is considered helpful, representatives from the BAC Secretariat will make every effort to participate. If you would like the BAC Secretariat to be present at your discussion, you may send an email to contactus@bioethics-singapore.org.

The BAC will be receiving feedback until 7 January 2008.

Scenario

Abi's father suffers from Parkinson's disease. Since his late 40s, her father started to experience muscle rigidity, tremors, memory loss and a slowing of movement. The family is concerned that he may lose physical mobility in a few years. From what she has been told, Parkinson's disease affects the nerve cells in a part of the brain that controls muscle movement. The exact cause is not known and there is also no cure for it.

Abi learnt that her niece, Carol, is part of a research team at Merlion Medical School (MMS) that is conducting embryonic stem cell research that could lead to a cure for the disease in the long run. However, the research is proceeding slowly due to a shortage of human eggs. Abi feels that she should donate her eggs to help advance the research even though the procedures involved are invasive and carries some health risk. While a cure

Figure 2. Public Consultation on Donation of Human Eggs for Research

may not be found quickly enough to help her father, future generations may benefit from the research.

Abi discussed her intention with her older cousin, Betty, who will be undergoing in vitro fertilisation (IVF) at Merlion Hospital. IVF is a clinical and laboratory procedure whereby the eggs and sperm from a couple are extracted and fertilised outside their bodies. Such a procedure is a kind of assisted reproduction aimed at increasing the chances of a couple conceiving a baby. After speaking with Abi, Betty is also thinking of contributing some of her eggs not used in her fertility treatment to MMS.

We would like to invite you to provide your views on the following:

(1) Do you think Abi, who is 35 years of age and a mother of three children, should be able to donate eggs to MMS for research? If Abi needs to take time off from her work so that she could donate her eggs, do you think she should be compensated (either fully or in part) for the loss of her income, inconvenience and risk involved? If so, what type of compensation would be acceptable and not amount to an inducement?

(2) Carol, who is 21 years of age, was inspired by her aunt Abi and she wants to donate her eggs to help advance the work of her research team. Do you think she should be allowed to do so? If she is, do you think she should receive any payment for the time, inconvenience and risk involved? Carol is a graduate student at MMS and does not receive an income.

(3) IVF is an expensive procedure, and even then, the couple undergoing the treatment may not be successful in conceiving a child. Eggs that are leftover from the treatment may be kept for future use, donated to other infertile couples, donated for research or destroyed. If Betty, decides to donate her "spare" eggs to MMS for research, do you think she should be subsidised by MMS for the cost of her IVF treatment?

Figure 2 (Continued)

The aesthetics of the narrative or the way in which it has been presented should be noted in that a strong association is made between the 'public' and a notion of the 'common good'. First, the main objectives of the consultation are clearly set out alongside the identity of the organization – essentially that of a public institution. In providing feedback, a respondent would be inclined to

feel that a service is being rendered as a citizen or perhaps as a member of an even broader community towards a common good. It may be argued that respondents are encouraged to adopt a position of trust, which is a standpoint whereby overt self-interest is discourage in favor of one that allows an assessment to be made for the benefit of another. From the narrative, the most direct beneficiaries would be women, from whom eggs are obtained, and society, through the advancement of science. Second, publicity for the various feedback channels – including the possibility of participation in focus group discussions organized by civic groups – was broadcasted through a press conference and in subsequent media reports, thereby suggesting an openness or receptiveness to a gathering of views from non-specialist quarters of society. Third, a notion of 'common good' bordering on altruism is implicit in the motives of the women in the narrative who were in a position to contribute eggs for research. A contrast may perhaps be made with the situation in South Korea, where nationalism was perceived to be a driving force behind egg donation for research – at least prior to the unraveling of the scandal around Professor Hwang.[733] It was in this overall setting that respondents were presented with a number of issues that related to the notions of 'compensation',[734] 'spare' eggs, 'inducement' and 'safety'. These issues may be generalized in the following manner:

(1) Whether a middle-aged woman with children should be able to donate eggs for research, and if so, whether she should be compensated for loss of income, inconvenience and risk involved;

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733 Leo Kim. Explaining the Hwang scandal: national scientific culture and its global relevance. *Science as Culture* (2008) 17:397-415, at 408, 410-411.

734 In the consultation paper, 'compensation' is defined as "recompense for presumptive loss of income and/or risk and inconvenience", whereas reimbursement relates to "repayment for incurred expenses": ED Report at A-20, footnote (3). These definitions have been retained in the ED Report (at 19). See also discussion in Paragraph 4.26 of the ED Report (at 21).

(2) Whether a young healthy woman should be able to donate eggs for research, and if so, whether she should be similarly compensated; and

(3) Whether a woman who contributed her 'spare eggs' from fertility treatment should be subsidized for the cost of her treatment.

At the end of the consultation, 47 entries were made (on an anonymous basis) at the online discussion forum and the e-consultation platform, although at least 12 entries, and possibly up to 20, of which could have been made by a particular individual. This respondent appeared to be supportive of egg donation by women for research, but much concern was expressed over payment that could lead to financial inducement and exploitation. A number of proposals were made, including procedural safeguards against inducement. For instance, a cap was proposed by this respondent on financial compensation if provided, and this amount should be centrally regulated.

On the first issue, the general view was that women should be free to decide whether to donate eggs for research, although there was concern over possible health risks and inducement to donate for monetary gain. As to the subject of compensation (the second issue in the scenario), there was general agreement to some compensation being provided to middle-aged donors as it was felt that these women should not be financially disadvantaged from contributing to the advancement of science, which was seen as a public good. As with the first issue, concerns were expressed over possible health risks and exploitation. In relation to the 21 year-old graduate student, the public was similarly of the view that compensation should be provided although the

risk of coercion and inducement was considered to be greater. This may be attributable to the Professor Hwang scandal in South Korea, which received wide media coverage. There was no agreement over what donors should be compensated for, but many were in favor of compensation for time. In addition, many respondents were against commercialization of the human body although a small number voiced support for it. The third issue related to a compensated egg sharing scheme (where researcher could subsidize the IVF treatment of a woman who agreed to contribute some of her eggs or embryos for research), which was recently allowed in the UK.[735] A majority of the respondents indicated that the cost of fertility treatment of a woman who donated her 'spare' eggs for research should be subsidized, although some strongly rejected this and regarded such a scheme as effectively commercialization.

The consultation paper did address many of the concerns of respondents, with the exception of (1) privacy of donors and the confidentiality of their personal information, (2) the provision of proper information to donors and in a manner that is effective in facilitating understanding, and (3) the availability of medical care for short-term and long-term adverse health consequences arising from the egg donation procedure. The third point was also raised in written responses from members of the public, including public institutions, to the key issues raised in the consultation paper.[736]

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735 UK Human Fertilisation and Embryology Authority. *Directions given under the Human Fertilisation and Embryology Act 1990: Giving and Receiving Money or Other Benefits in Respect of Any Supply of Gametes or Embryos*. 2006.

736 These respondents were Graduates' Christian Fellowship (at C-11 of ED Report), Institute of Mental Health (at C-16 of ED Report), Law Society of Singapore (at C-20 of ED Report), Dr Chuah Khoon Leong (at C-48 of ED Report), Dr Suresh Nair (at C-69 of ED Report) and Professor George Wei (at C-102 of ED Report).

A majority of the respondents was in favor of allowing healthy women to donate eggs for research. Those who opposed were mostly motivated by religious concerns, although some (such as the Singapore Nursing Board) did not consider the benefit to outweigh the health risk entailed. Those who considered egg donation to be similar to participation in a clinical trial, compensation for risk should be provided. Others were concerned about inducement, and proposed some form of insurance scheme to be implemented as compensation for risk.[737] There was also some support for compensation for inconvenience, and one respondent proposed compensation for emotional and psychological harm.[738] In addition, two respondents proposed incentives to be provided in order to encourage women to donate eggs for research. For instance, one respondent proposed a complimentary oocyte banking scheme to encourage career-minded women to donate unused eggs for research.[739] Compensated egg sharing scheme was supported by four respondents, but opposed by at least one institution and one individual.[740]

A number of conditions relating to informed consent that were presented by respondents. One such condition was that consent should be taken by an independent third party. There should be clear discussion on vulnerable groups, which in this case would include not only children and the mentally incapacitated, but also people who are in economically, socially or by employment vulnerable position where there might be some degree of coercion (such as the graduate students

737 There was no agreement on whether risk should be compensated as it was supported by two respondents (such as the Institute of Mental Health and Dr Alexis Heng) but opposed by some members of the IRB of the National Dental Centre.

738 Dr Alexis Heng, Associate Professor Allen Yeoh and some members of the IRB of the National Dental Centre indicated that compensation for inconvenience should be provided. Mr Patrick Goh proposed that compensation should include any emotional or psychological harm (ED Report, at C-50).

739 Feedback from Dr Suresh Nair: ED Report, at C-4 and C-5.

740 Prof Christopher Chen (ED Report, at C-8), some members of the IRB of the NDC (ED Report, at C-34), Dr Alexis Heng (ED Report, at C-61 to C-64) and Dr S Nair (ED Report, at C-68 and C-69) expressed support for the "compensated egg sharing scheme", but this scheme was explicitly opposed by the National Council of Churches of Singapore (ED Report, at C-32) and by Professor Chan Soh Ha (ED Report, at C-47).

in the South Korean incident). Notwithstanding the research focus, this would be similar to the practice in IVF treatment.[741]

Concerning the sale of eggs, there was unanimity among respondents that commercialization of any part of the body, including eggs, should be prohibited. Clear regulatory mechanisms were proposed in response to the fourth issue. Members of the legal community indicated that the current regulatory scope might be lacking in its reach, and that it should encompass all biomedical research in Singapore. It was further proposed that egg donation be limited to Singaporeans and permanent residents in view of the significant socio-economic gap between these classes of women and foreign workers. Other comments included a compensatory mechanism for adverse events, including some form of mandatory no fault based insurance coverage.[742] Feedback from the public consultation makes clear that the risk account provided by the BAC has been made 'real', so that public focus shifted to concerns over undue inducement and exploitation. In the next section, we consider further the performative aspect of the consultation process, and its constructive function.

5.5 'White-Washing' and an Emergent Civic Epistemology

In her study of political scandals regarding risks to health and security in France during the 1990s, Violaine Roussel observes the emergence of a new public definition of risks, and correspondingly, the responsibility of political decision-makers for them. The locus of this new

741 Fieldnotes, 16 January 2008, M7.

742 The Law Society of Singapore (ED Report, at C-21) and Dr Suresh Nair (ED Report, at C-69) suggested that compensation for risk can take the form of mandatory insurance.

politics lies in the constitution of validation networks:[743] "The discourses of scandal respond to different validity registers depending on the institution – judicial, political, scientific, media – involved. Therefore actors think and act according to social markers that are not standardized or unified. The representations of precaution and risk in medical research refer, for example, to the unavoidable existence of uncontrollable factors, in the context of scientific controversies and uncertainties, whereas other visions of uncertain situations and their effects compel other actors to different behaviors." Under a neo-liberal paradigm, Roussel argues that the creation of the French Agency for Sanitary Security for Food is a political technology of political actors to evaluate, control and if possible, exclude risks and to avoid public prosecution of any failure to discharge its official duties. Through political tools that include local risk prevention plans, epidemiological surveillance networks and committees on public health or security problems, politicians attempt to render the reality of risks visible to everyone, and to themselves. The endeavor to show that these risks are being dealt with could lead to overtly disproportionate responses, such as the extermination of almost 50,000 animals that had been in contact with English sheep suspected of having food and mouth disease, although no ill sheep was identified in France.[744] Alan Hunt elaborates on the neoliberal agenda, where individuals are compelled to assume the role of moral entrepreneurs of the self.[745] By this logic, individuals as stakeholders become – as Michael Power argues – critical in the definition of risks and responsibilities.[746] Ironically, individuals are often neither all-calculative nor fully informed or interested, so that precautionary (public) activities are directed not at reducing risks, but eliminating them,

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743 Violaine Roussel, New Moralities of Risk and Political Responsibility. In Richard V Ericson and Aaron Doyle (eds), *Risk and Morality*. Toronto, Buffalo and London: University of Toronto Press, 2003, pp 117-144, at 135.

744 *Ibid*, at 140-141.

745 Alan Hunt, Risk and Moralization in Everyday Life. In Richard V Ericson and Aaron Doyle (eds), *Risk and Morality*. Toronto, Buffalo and London: University of Toronto Press, 2003, pp 165-192.

746 Michael Power, Risk Management and the Responsible Organization. In Richard V Ericson and Aaron Doyle (eds), *Risk and Morality*. Toronto, Buffalo and London: University of Toronto Press, 2003, pp 145-164.

especially where precaution, driven by a permanent state of anxiety and fear, gives emphasis to catastrophic potentials.[747]

Corporate law in the UK and in Singapore provides for a 'white-washing' procedure whereby financial assistance by a company for the purpose of acquiring its own shares or the shares of its holding company becomes permissible after complying with a number of procedural requirements, including the publication of a notice setting out certain requisite information in a major newspaper.[748] It appears to me that public consultation is similar to the 'white-washing' procedure in that it is composed of public acts that are performed in order to be exonerated from certain 'risks' of harm that cannot be effectively removed. As we have discussed, risk to health in egg donation – like any other participation in clinical trials – cannot in most cases be entirely extinguished. In order to allow the research in the public interests, risks are then re-conceptualized and communicated as occurrences that one can voluntarily (and out of altruism) agree to assume through participation in the research. Hence, informed consent has become an all-important requirement in ethics and in law. To add legitimacy to this arrangement, the public must come to accept that such risks that are inherent to participation in biomedical risk can be voluntarily assumed for the common good, but subject to the conditions that the BAC would prescribe on behalf of the 'public'. Public consultation is in this respect a 'white-washing' process. This is all the more so, given that the 'public' has no consistent meaning or constituents. However, it is insufficient to think of public consultation as only a means of public exoneration. Arguably, it is more fundamentally a civic epistemology.

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747 Kevin D Haggerty, From Risk to Precaution: The Rationalities of Personal Crime Prevention. In Richard V Ericson and Aaron Doyle (eds), *Risk and Morality*. Toronto, Buffalo and London: University of Toronto Press, 2003, pp 193-214.

748 Section 76, *Companies Act*, Chapter 50 of Singapore Statutes (2006 Revised Edition). See also *Public Prosecutor v Lew Syn Pau and Another* [2006] SCHC 16.

In a paper that discusses Singapore's initiative to promote the biomedical industry, Kerry Holden and David Demeritt presented a critical view of the country's 'developmental state' political culture, which stood in contradiction to a climate of liberal democracy within which the scientific enterprise is said to have thrived. While observing that 'good science' now also depends on being seen to observe certain ethical terms and conditions, they suggest that "the practice of ethical review was not driven by much consideration for the ethical concerns that the Singaporean people may have about biomedical research. Rather, it was largely about complying with international bureaucratic standards and procedures, so that the resulting data could be used in drug licensing applications in the major markets of the US and Europe".[749] The existence of a 'public' was explicitly called into question, without considering efforts that have been made by the BAC to engage with the Singaporean public since 2001. The difficulty with this approach is that it presents a notion of 'public' that is too static and essentialised, and also quite contrary to the approaches in STS.

STS presents a citizen as possessing varied knowledge systems located in particular practices, subjectivities and identities. Such knowledge systems may be specialist ones, non-specialist or lay knowledge systems, or experience-based expertise. While it is recognized that different forms of expertise are not readily combined, scientific knowledge is regarded as effectively cultural in that it "embodies, reflects and projects commitments of a human kind, which also shape human relations and identifies, imagined communities and ontologies".[750] Practicing citizenship is

[749] Kerry Holden and David Demeritt. Democratising science? The politics of promoting biomedicine in Singapore's developmental state. *Environment and Planning D: Society and Space* (2008) *26*, 68-86, at 80.

[750] Melissa Leach, Ian Scoones and Brian Wynne. Introduction: science, citizenship and globalization. In *Science and citizens: Globalization and the challenge of engagement*, edited by Melissa Leach, Ian Scoones and Brian Wynne. London and New York: Zed Books, 2007, pp 3-14, at 12-13.

regarded in turn as a learning process.[751] Limited accessibility here provides an occasion for criticism, but it is questionable if there is any deliberative forum that is not defined within a framework that silences other perspectives or agenda.[752] Issues that are raised as a matter of public concern implicate certain actors jointly and antagonistically.[753] There are not many issues that could be framed in such a manner as to be of practical relevance to every member of a society. Neither would it be sensible to consider a society to be 'democratic' only if its members could (and would be willing) to vote on every sort of issue that may have some implication on them. Furthermore, globalization has contributed to greater diversity in the framers of issues that relate to stem cell science and technology.

When the BAC undertook the task of considering the ethical, legal and social implications of stem cell science and technology, there already was active debate on the subject in the global forum. The very premises defined in the ethical, legal and social are those widely employed in the industrialized West and in a number of countries in East Asia. Like genetics, stem cells became what Sarah Franklin considers to be a "global biological", replete with imagery of technological potency, human frailty and future salvation.[754] The situation for human eggs in the

751 *Ibid*, at 30-31.

752 *Ibid*, at 30.

753 Noortje Marres, The issues deserve more credit: pragmatist contributions to the study of public involvement in controversy. *Social Studies of Science* (2007) *37*, 759-780, at 772-773. See also Noortje Marres, Front-staging Nonhumans: Publicity as a Constraint on the Political Activity of Things. In Bruce Braun and Sarah J. Whatmore (eds), *Political Matter: Technoscience, Democracy, and Public Life*. Minneapolis and London: University of Minnesota Press, 2010, pp 177-209. Drawing on John Dewey's notion of the 'public', Marres argues that 'green technologies' such as long-life bulbs and energy-efficient domestic appliances act as political mediators of green governmentality on the one hand and of civic practices on the other. Material harm, made 'real' by electric meters and energy standards, contributes to the formation of a 'public' that does not other map neatly with any other social groupings.

754 Sarah Franklin, Stem cells r us: emergent life forms and the global biological. In Aihwa Ong and Stephen J Collier, *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems*. Singapore: Blackwell Publishing, 2006, pp 59-78, at 61.

ED Consultation Paper and ED Report was no different. Hence the BAC would not have had a free hand in framing the issues for public consultation on either subject.

Given the myriad of interests, meanings, hopes, and concerns – both global and local – that constitute stem cell science and technology (as also discussed in Chapters 2 and 3), public accessibility has presented significant practical challenges to policy and bioethical bodies like the BAC. Whereas the outreach of the BAC has been broad, the responses elicited appear to comprise a consistent group of core institutions. There could be a few reasons for this. First, many of the social roles that were performed by civic organizations have been progressively subsumed within the various instruments and organs of the state. Second, individual members of society – even highly qualified ones – consider their personal views to be of insignificant weight and would prefer to speak on behalf of, or otherwise as part of, a group or institution. Third, the deliberative 'space' that is created in the consultation papers give emphasis to a notion of citizens as socially embedded and membership within a community. This element is arguably present even in the more generic REACH online consultative platform. Hajer's observation on the performative aspect of decision-making in rebuilding Ground Zero is pertinent: "It is the very stagedness here that creates the power of the deliberative moments: by virtue of being staged they have generated a moment in the public consciousness."[755] Fourth, the state is generally perceived by members of the public as coherent and rational, even if restrictive on issues that are regarded as politically sensitive.[25] But as Stephen Hilgartner notes,[756] champions of transparency sometimes romanticize openness, without adequately considering the merits of institutional

[755] Maarten A. Hajer. *Authoritative governance: Policy-making in the Age of Mediatization*. New York: Oxford University Press, 2009, at 185.

[756] Stephen Hilgartner. *Science on stage: expert advice as public drama*. Stanford: Stanford University Press, 2000, at 149-150.

procedures or fully recognizing the ubiquity and inevitability of information control. He persuasively argues that the fundamental choice is not between the transparent or the opaque, but different systems that shape the role of experts and audience, and different ways in which science is presented on the public stage. Sheila Jasanoff advances a similar point, in her indication that "America's particular democratic settlement, in which public claims are continually tested by skeptical citizens and journalists…the very idea of public demonstrations as a space of experiment is culturally particular, not universal, way of engaging citizens. It assumes that disclosure and transparency are *possible*, and that people have the will, the means, and the competence to evaluate the claims and proofs presented to them".[757]

In East Asia, it has been noted that STS scholars have began reflecting on the limitations of a deliberative model of public participation that they have enthusiastically promoted.[758] Commenting on three papers that address citizen participation in relatively disparate areas of science and technology, Brian Wynne's observation of the inadequacies of conventional visions and practices of public participation is instructive: "Not only is it *not* a matter of claiming that publics know as well as experts in their specialist field; we should also not operate in the belief that citizens have well-articulated imaginations about what they believe to be desirable or possible in domains such as health, energy, agriculture and food. Thus to expect such inputs as a currency of participation processes is optimistic, even if searching and salient questions will be posed of experts posing their own such imaginations".[759] In the light of these arguments,

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757 Sheila Jasanoff. *Designs on nature: science and democracy in Europe and the United States*. Princeton and Oxford: Princeton University Press, 2005, at 263 (emphasis in text).

758 Dung-sheng Chen and Chia-Ling Wu. Introduction: Public Participation in Science and Technology in East Asia. *East Asian Science, Technology and Society: an International Journal* (2007) 1: 15-18, at 18.

759 Brian Wynne. Public Participation in Science and Technology: Performing and Obscuring a Political-Conceptual Category Mistake. *East Asian Science, Technology and Society: an International Journal* (2007) 1: 99-110, at 107.

Massimiano Bucchi and Federico Neresini provide an instructive overview by mapping the different forms of public participation given varying degrees of spontaneity and intensity of participation in the process of knowledge construction. They insightfully observe: "If the "anaesthetization" of politics by the massive injection of technoscientific expertise has not been sufficient to deal with crucial dilemmas, this is not a reason to expect that those same dilemmas will be solved simply by injecting democratic arrangements into science, especially if democracy is defined with its most simplistic meaning of "majority voting"."[760]

The 'public' that has emerged from the SC Report and the ED Report share certain features with Annelise Riles 's PAWORNET. In her study, Riles observes that networkers did not understand themselves to share a set of values, interests or culture. Instead, they understood themselves to be sharing in their involvement in a certain network that was a form of institutionalized association devoted to information sharing.[761] What defined networkers most of all was the fact that they were personally and institutionally connected or knowledgeable about the world of Pacific institutions and networks. In particular, it was the work of creating documents, organizing conferences, or producing funding proposals that generated a set of personal relations that drew people together and also created divisions of its own. The 'public' of the SC Report and the ED Report comprised institutions and a number of individuals – often institutionally connected – that represented a diverse set of values, interests and perhaps culture (construed in terms of their day-to-day practices in the least). This resembles a network in a number of ways. They were brought into a particular set of relationship within a deliberative space created in the main by the

[760] Massimiano Bucchi and Federico Neresini, Science and Public Participation. In E.J. Hackett, O. Amsterdamska, M. Lynch and J. Wajcman (eds), *The Handbook of Science and Technology Studies*. Cambridge MA: MIT Press, 2008, pp 449-472, at 461-464 and 466.

[761] Annelise Riles. *The network inside out*. Michigan: University of Michigan Press, 2001, at 58-9, and 68.

consultation papers and reinforced through a variety of means that included public meetings, conferences and feedback sessions. Arguably, even individual feedback from REACH encompasses a certain kind of pre-existing (sub-) network that has been formed with a view to soliciting relatively more "spontaneous and independent, uninvited forms of civil participatory action". But this 'network' is not a static one. It varies with, but also shapes, the broader phenomenon of science and expectations as to how science ought to be engaged. In this connection, Riles's observation is instructive: "It is not that networks "reflect" a form of society, therefore, nor that society creates its artifacts… Rather, it is all within the recursivity of a form that literally speaks about itself".[762] To better appreciate science and its 'public' (that is, citizens who engage with it), one should also appreciate the attending (and emergent) civic epistemology.

The BAC was not established primarily to engage the public; public involvement was subsequently seen to be vital for reasons that include the filling of epistemological 'gaps' in institutional knowledge, and to secure broader legitimacy on an initiative that will not yield immediate benefit to the public. Arguably, a civic epistemology that has taken shape since 2001, particularly in a deliberative space initially developed as a moderate gradualist platform that was grounded in certain values regarded by the BAC as critical to facilitate participation. This initiative contributed to the formation of a 'public' in that a set of social relations emerged in the way that the BAC interacted with a diverse constituency of respondents. Ethical constructs (like 'embryo' and 'egg') and language (centered around a notion of 'respect for persons') became essential components of a recursive form of an emergent civic epistemology, or a generally accepted or recognized basis by which the 'public' would think about and engage stem cell science and technology. More recently, several events leading up the BAC's recommendations

[762] *Ibid*, at 69.

for egg donation contributed to the development, as well as refinement, of ethical constructs and language. A 'learning curve' (not confined to policy-makers and regulators, as considered in Chapter 4) was also evident in that a number of respondents, especially those from religious groups, felt that they were better able to engage in ethical deliberation outside of their particular belief systems. As noted earlier, a number of respondents to the consultation on egg donation voiced the need to explicitly provide for privacy safeguards. The BAC might have considered an explicit mention to be unnecessary as the concern would have been addressed in an earlier report,[763] although its mention and subsequent incorporation into the ED Report reflect learning and application of ethical goals and language. It is accordingly insufficient to consider the BAC's public consultation exercise as only a 'white-washing' process, but necessarily the component of a broader and emergent civic epistemology. This is a dynamic and recursive process, as is our knowledge of 'risk' and 'public'.

5.6 Anticipatory Knowledge as Civic Epistemology

To pick up on Michael Power's point on addressing 'risk' as a form of learning and experimentation rather than rule-based processes, the construction of women as 'risky objects' and the articulation of possible harms and dangers as 'risks' involve the generation of 'anticipatory knowledge', which is defined as "social mechanisms and institutional capacities involved in producing, disseminating, and using such forms [as]...forecasts, models, scenarios, foresight exercises, threat assessments, and narratives about possible technological and societal

[763] Bioethics Advisory Committee, *Personal Information in Biomedical Research*. Singapore: Bioethics Advisory Committee, 2007.

futures." In other words, they are about knowledge-making about the future.[764] Drawing inspiration from Ian Hacking's 'looping effect', where knowledge of psychiatric diagnosis may alter the patient's psychological experience, Nelson, Geltzer and Hilgartner observe that anticipatory knowledge does not merely represent the future, but inevitably intervenes in it.[765] As we shall see, the consistency of public concerns with those identified by the BAC may well reflect the Thomas theorem, where real consequences follow when something (albeit imaginary) is treated as real.[766]

Hugh Gusterson conceptualizes anticipatory knowledge as a means to gap-filling (we considered earlier that public consultation has this function as well). His study relates to the Reliable Replacement Warhead (RRW) program, where US weapons laboratories could design new and highly reliable nuclear weapons that are safe to manufacture and maintain. Initiated by the US Congress in 2004, Gusterson shows that struggle over the RRW occurred across four intersecting "plateaus of nuclear calculations" – geopolitical, strategic, enviropolitical and technoscientific – each with its own contending narratives of the future. He indicated that "advocates must stabilize and align anticipatory knowledge from each plateau of calculation into a coherent-enough narrative of the future in the face of opponents seeking to generate and secure alternative anticipatory knowledges".[767] Hence the *interconnectedness* of the four plateaus of calculation, including the tradeoffs entailed, was evident in the production of anticipatory knowledge vis-à-vis the RRW program. In addition, the issues of *performativity* and "*social construction of*

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764 Nicole Nelson, Anna Geltzer and Stephen Hilgartner, Introduction: the anticipatory state: making policy-relevant knowledge about the future, *Science and Public Policy* (October 2008) 35, 8: 546-550, at 546.

765 *Ibid*, at 547 and 550.

766 William I. Thomas and Dorothy S. Thomas. *The child in America: Behavior problems and programs.* New York: Knopf, 1928, at 571-572.

767 Hugh Gusterson, Nuclear futures: anticipatory knowledge, expert judgment, and the lack that cannot be filled. *Science and Public Policy* (October 2008) 35, 8: 551-560, at 553.

ambiguity" were also evident.[768] Gusterson observes that being craft items, no two nuclear weapons are exactly alike. However, the proscription of testing through detonation meant that both performativity and ambiguity (referred to as 'social construction of ambiguity') over reliability became matters of speculation, determined through extrapolation from the past to fill knowledge 'gaps' in the present and future. This attempt at anticipatory knowledge creation also prescribed a form that the future was to take.[769] Although anticipatory knowledge as foreknowledge can be a useful tool for international organizations and national policymakers to cope with lack of information, conflict could arise over the generalizability of foreknowledge. Manjari Mahajan shows this in the contention between international health organizations and Indian bureaucrats over the actual epidemiological risks posed by AIDS in India. Foreknowledge as what is already conceptualized and "equipped with prior models, categories and information" leaves little room for the unexpected.[770] It could thereby privilege a globalized anticipatory knowledge over national policy-making, even if the former might not be true or appropriate in a particular location.

As we have considered in the earlier sections of this chapter, the BAC's understanding of quantifiable risks has been largely shaped by foreknowledge of a foreign (mainly US) source. This did not preclude national policy-making as a significant degree of unquantifiable risks remained. The issues raised by the BAC in the ED Consultation Paper and the scenario that it

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768 *Ibid*, at 558-9.

769 *Ibid*, at 558-9 (footnote). Gusterson observes: "Anticipation, then, takes on a Heisenbergian dimension as a form of knowledge that not only guesses about events in the world but directs them in unintended but unavoidable ways. In such a situation, the knowing guess is never innocent. The natural inclination to 'play it safe'…may end up, through the feedback loops that connect the anticipated with the actual, enacting the less safe world against which playing it safe was a hedge. The search for insurance against disaster may become insurance of disaster."

770 Manjari Mahajan, Designing epidemics: models, policy-making, and global foreknowledge in India's AIDS epidemic, *Science and Public Policy* (October 2008) 35, 8: 585-596, at 594.

presented in soliciting public feedback were essentially anticipatory of a number of challenges it envisaged. At a normative level, it was concerned that in adopting a more liberal attitude towards payment for eggs would be a move in the direction of commercializing the human body. More immediately, the BAC was concerned with the exploitation of under-privileged women. Hence the account provided by the BAC could also been seen as an 'anticipatory knowledge' strategically deployed to counter competing (primarily neoliberal) knowledge claims of proponents for the greater monetization of research.[771] Being a placeholder-type of foreknowledge that falls outside of its constituent 'expertise', a greater need for transparency and clarity was perceived, mainly to secure its legitimacy. The often lack of transparency and clarity (even at the point of origin) over anticipatory assumptions and objectives is a well-recognized problem in the construction of anticipatory knowledge. Kathleen Vogel provides an illustration of how the quasi-journalistic reporting of gathered intelligence led to an erroneous assessment of Iraq's bioweapons capability.[772] She highlights the need to be reflective of the cumulative (temporal and material) effect of anticipatory frames and the practices undergirding them in order to understand and mitigate intelligence failures.[773] Iain Wilkinson similarly observes that risk discourse in the technical domain "largely concerns the identification of criteria for upholding an 'objective' account of the probable occurrence of specific events of adversity...[and one] should be careful to pay heed to the extent to which the agendas for risk research are

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771 This version of 'anticipatory knowledge' as knowledge marshaled by political teams in anticipation of the knowledge claims of rival teams is proposed by Tara Schwegler. Tara A. Schwegler, Take it from the top (down)? Rethinking neoliberalism and political hierarchy in Mexico, *American Ethnologist* (November 2008) 35, 4: 682-700.

772 Kathleen M. Vogel, 'Iraqi Winnebagos™ of death': imagined and realized futures of US bioweapons threat assessments, *Science and Public Policy* (October 2008) 35, 8: 561-573, at 568. While drawing of mobile labs may be the 'immutable mobiles' in Vogel's paper, they take on more varied forms in my research, including images of 'chimeras' and 'hybrids', and more importantly ethical principles that critically define the almost unquestionable disciplined space within which ethical facticity arises.

773 Ibid, at 571. Vogel notes further (at 572): "…one needs to be reflective of the social processes comprising knowledge production, to see how different organizational frames and practices can lead to particular kinds of knowledge being produced to inform the prediction of future threats".

determined by sectorial interest groups that have no desire to pursue questions relating to who has the legitimate power to decide which risks should be prioritised and how issues of 'social benefit' and 'technological progress' should be defined."[774] This in turn presents question of priority and transparency in public domain, particularly the need to consider what has been left out, notably the 'social' and the quality of personal relationships.

5.7 Report on the Donation of Human Eggs for Research

Following the public consultation, the ED Report was published by the BAC on 3 November 2008 following the completion of the 2-month public consultation that commenced on 7 November 2007. Given the central relevance of cloning technology, its main mechanics was again explained in the ED Consultation Paper.[775] The ED Consultation Paper also stated that a woman should be free to decide whether to make the donation "regardless of her health status", but subject to meeting legal and ethical requirements.[776] In the ED Report, the same point was made by invoking the principle of respect for individuals, but with emphasis on the informed and voluntary nature of the giving, and effective safeguards against exploitation. Procedural safeguards were given prominence, although the BAC recognized that they are not foolproof in that vigilance on the part of the regulator is still necessary.[777]

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774 Iain Wilkinson, *Risk, Vulnerability and Everyday Life*. London and New York: Routledge, 2010, at 92-93, and 95.

775 Paragraph 15 at pp. A-7 and A-8 of the ED Report.

776 Paragraph 33, at A-12 of ED Report.

777 Paragraphs 4.14 and 4.15, at pp. 15 and 16 of the ED Report.

In addition, the ED Report recommends that women donating eggs for research should be reimbursed for expenses incurred and compensated for loss of time and earnings as a result of the procedures required to obtain the eggs.[778] Compensation for inconvenience proposed in the consultation paper was not taken up in the ED Report, due to the arbitrary nature of the claim and difficulty in administration. Non-commercialization of eggs was emphasized, as this was regarded as necessary to avoid putting women at risk of exploitation, and which is a goal that is consistent with the principle of safeguarding the welfare of all research participants.[779] Should an egg donor suffer from any medical complication as a direct and proximate result of the donation, she should be provided with prompt and full medical care.[780] This provision gives effect to public feedback on the need to ensure that medical care is available for adverse health consequences arising from the egg donation procedure. Responsibility for this provision rests with the researchers and their institutions.[781] The recommendation to allow limited compensation for healthy donors represents a departure from Section 13 of the *Human Cloning and Other Prohibited Practices Act*, which specifies that a person is prohibited from giving or receiving valuable consideration for the supply of human eggs or embryos, or to otherwise make an offer to that effect. Valuable consideration has been defined as including any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply. Reasonable expenses have in turn been defined to include expenses relating to the collection, storage or transport of the embryos.

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778 Recommendation 6 of the ED Report.

779 See especially the discussion in paragraphs 4.16 to 4.21 of the ED Report, at 16 and 17.

780 A general description of the healthcare system in Singapore is available at the website of the Singapore Ministry of Health: http://www.moh.gov.sg/mohcorp/hcsystem.aspx.

781 Recommendation 5 of the ED Report.

In the ED Report, the BAC maintains that the ethical requirement for the donation of tissue (which includes embryos) for research to be outright gifts is not compromised so long as the contribution is not tainted by any inducement. The giving of eggs for research retains the character of altruistic gifting, so long as compensation that is directed at ensuring the financial neutrality of the contributor does not amount to an inducement to make the contribution. In other words, the fair treatment of women who donate their eggs solely for research is the primary justification for allowing compensation to be provided for loss of time and earnings that are consequential to the donation. The BAC emphasizes that a donor should not be made worse off by her altruistic giving, but it acknowledges the challenge of having to distinguish the provision of reasonable payment to donors, from inducing women to provide eggs for monetary gain. Following this rationale, the BAC indicates that women should not be compensated for the donation of eggs for research when these are surplus to the treatment or obtained as a result of other medical treatments. As the risk, discomfort and lost time are already an inherent part of the treatment, no additional discomfort or inconvenience would have been assumed to donate these eggs for research. It was on this basis that the BAC did not consider the 'compensated egg sharing' schemes adopted in the UK to be acceptable in Singapore.[782] This might have also been the basis of the BAC's strict reading of 'inducement' in that it does not agree with the proposition that not every inducement is undue.[783]

Perhaps a key issue in this ethical deliberation is whether eggs could be regarded as 'spare' in the way that a tumour that has been surgically extricated could be so considered. If the issue had

[782] Benjamin Capps and Alastair Campbell. Why (only some) compensation for oocyte donation for research makes ethical sense. *Journal of International Biotechnology Law* (2007) 4, 89-102.

[783] Ezekiel Emanuel, Xolani Currie and Allen Herman, on behalf of Project Phidisa. Undue inducement in clinical research in developing countries: is it a worry? *Lancet* (2005) 366: 336-340, at 336.

been decided in the negative, then there could be two implications. First, this would suggest that some form of payment ought to be made to women who contributed eggs for research because these eggs are not 'spare' (and by implication, unwanted) tissue from a medical procedure.[784] Second, it further suggests that these donors ought to be treated no differently from participants in a clinical trial, and in respect of which significant sums of money – to much ethical controversy – have been given to trial subjects. Indeed, this has been the conclusion that was reached by some.[785] For instance, this position was adopted by the European Society on Human Reproduction and Embryology Task Force on Ethics and Law,[786] and it may have been a justification for some organizations to provide a relatively large sum of money to egg donors for research.[787] The main difficulty with this position is that it brings to the fore the difficulty of distinguishing compensation from inducement, and any decision made in that connection may have serious repercussions on payments that are currently allowed for participation in clinical trials.

The ED Report makes clear that eggs could be 'spare' in that they are surplus to the fertility treatment and, in such a scenario, the giving of eggs for research should not be on a compensated

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784 Roberts and Throsby argue that 'fresh' eggs are never 'spare' and this could be a justification for the compensated egg sharing scheme, which the UK Human Fertilisation and Embryology Authority has endorsed. The late Anne McLaren shared this position and thereby argued that scarcity of human eggs could be a basis for allowing human-animal combinations such as cytoplasmic hybrids to be created. See Celia Roberts and Karen Throsby. Paid to share: IVF patients, eggs and stem cell research *Social Science & Medicine* (2008) 66:159-169; and Anne McLaren. Free-Range Eggs? *Science* (2007) 316:339.

785 Ballantyne and Lacey argue that if women are asked to provide eggs for commercial stem cell research, they should be fairly compensated for their contribution. Dickenson (2007:67-82) goes further in proposing some degree of property interest to be conferred as the protection of women's interests in oocyte donation by way of contract alone is considered to lack robustness. See Angela Ballantyne and Sheryl De Lacey. Wanted – Egg donors for research: a research ethics approach to donor recruitment and compensation. *The International Journal of Feminist Approaches to Bioethics* (2008) 1, 145-164; and Donna Dickenson. *Property in the body: feminist perspectives*. Cambridge: Cambridge University Press, 2007.

786 European Society on Human Reproduction and Embryology Task Force on Ethics and Law. Oocyte donation for non-reproductive purposes. *Human Reproduction* (2007) 22, 1210-1213, at 1213.

787 Some of the organizations that allow compensation to be paid to donors of eggs for research have been considered by the BAC in its consultation paper: see A-16 and A-17 of ED Report.

basis. Such a position is consistent with the BAC's view that any contribution of tissue for research should be by way of gifting made altruistically. This further avoids the ethically problems of inducement and commercialization of the human body. However, the BAC recognizes that in a situation where a healthy woman should decide to donate eggs for research, she should be compensated for loss of time and earnings from undergoing the egg retrieval process. As we have noted, the main justification for this stance is one of fairness – the donor should not be financially disadvantaged by the giving.[788] Furthermore, the egg donation procedure is a very invasive one. While the eggs that are given in this context are not 'spare', healthy donors are not regarded as clinical trial subjects because the risks associated with the procedure are quantified (whereas there is greater uncertainty from participation in clinical trials)[789] and researchers are required to insure these donors against any complications that occur as a "direct and proximate result" of the donation.[790] While there may be a residual long term risk that is as yet not quantified or is indeed unquantifiable, altruism requires that such a risk be borne by the donor, who has not acted under any compulsion. It may be argued that rather than focusing on particular health risks, the BAC has instead directed its attention to addressing more

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788 The BAC's broader conceptualisation of 'payment' that should be made to healthy donors is arguably not too different from Charis Thompson's recommendation that "we compensate egg donors as a means of minimizing risks to donors, encouraging donations for the right reasons and under the best conditions of informed consent…and preventing trafficking in eggs". See Charis Thompson. Why we should, in fact, pay for egg donation. *Regenerative Medicine* (2007) 2, 203-209.

789 The US NRC and IOM suggest that medical risks of human egg donation are quantifiable and manageable. This view is not shared by others who argue that there is residual risk that could be unquantifiable and significant (see for example Dickenson and Idiakez). It should also be noted that some members of the public indicated in their feedback that compensation for risks would not be adequate. See National Research Council and Institute of Medicine. *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research*: *Workshop Report*. Washington DC, 2007; and Donna Dickenson and Itziar A. Idiakez. Ova Donation for stem cell research: an international perspective. *The International Journal of Feminist Approaches to Bioethics* (2007) 1, 125-144.

790 The words "direct and proximate" mirror those in Section 100095(c) of *The CIRM Medical and Ethical Standards Regulations* of the California Institute of Regenerative Medicine, Title 17, California Code of Regulations, 2011.

generally the safety of donors as a welfare concern. This construction of 'safety', 'spare' eggs and 'inducement' has in turned led to a particular set of procedures on consent taking.[791]

5.8 Overcoming Individualization in Risk Objectification

As with Weber and his followers, Power considers the concept of 'risk' to relate to an individualization process, which focuses on personal, legal and reputational risks.[792] Rather than attributing this superficially to conditions in a highly legalized society, he considers the problem (at least in the context of the UK) to relate more fundamentally to responsibility aversity – a critical manifestation of cultural conditions that encourage "a high appetite for risk, because of the attraction of positive outcomes, and a low appetite for responsibility and blame in the face of negative outcomes".[793] Power observes that defensive proceduralism arises when the 'risk game' becomes a 'blame game'. He further points out that defensive preoccupation with reputational and legal risks has little to do with any direct possibility of legal action. Instead "legal and other norms get embedded into organizational routines not because the real risks of litigation are well understood, but because the mere possibility creates a defensive orientation towards the need to justify decisions in retrospect".[794] Such a phenomenon becomes even more problematic as those (such as accountants) whose responsibility relates directly to risk management are themselves preoccupied with reducing risks to themselves.[795] Power is particularly concerned that this

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791 A relatively comprehensive discussion was taken up in the ED Report that culminated in Recommendations 2 to 4; see pp 12-15 of the ED Report.

792 Michael Power, *The Risk Management of Everything: Rethinking the politics of uncertainty*. London: Demas, 2004, at 13-14.

793 *Ibid*, at 45.

794 *Ibid*, at 46-7.

795 *Ibid*, at 48.

overwhelming focus on risk management is a threat to democracy and public life, as democratic processes and government become subsumed within administrative paradigms. He refers to Mary Douglas for a counter-intuitive observation. Where risks suggest inevitability or absence of choice, Douglas has indicated that "we choose what to fear in order to support our way of life".[796] To counter what he perceives to be a negative development, Power's proposals include (1) a re-characterization of risk management as a form of learning and experimentation rather than rule-based processes, thus placing stronger reliance on human capabilities to imagine alternative futures instead of quantitative ambitions to predict the future; and (2) counter the individualization process by developing public understandings and 'civic epistemologies' of how risk issues are processes and potentially amplified by the institutions of media and law. A broader political culture must communicate an understanding that not every risk is controllable and that expert opinions are not infallible. It should also provide the necessary institutional conditions or "safe haven" for the exercise of professional and expert judgments in honest and reasonable decision-making.[797]

Conservatism in attitude towards risk is dependent on the positionality of the party concerned and the interests that are at stake. As we have discussed, the significance of positioning and its impact on risk appetite was noted by Mary Douglas and Aaron Wildavsky. More recently, and also drawing on prospect theory, Barbara Vis's study of the politics of welfare state reform in the Netherlands suggests that policy-makers (as well as voters) will avoid risk if they consider themselves to be in a domain of gains and when they see their status quo as still acceptable or tolerable. In contrast, they are more likely to opt for gamble when they view their current

796 *Ibid*, at 55-56 and 60.
797 *Ibid*, at 61-65.

situation as a loss. She sets this out summarily as:[798] "Governments in a gains domain pursue absolute gains and are unwilling to engage in risky reform efforts, while governments in a losses domain pursue relative gains and are more willing to accept the risks of reform." One could perhaps think of positioning and positionality as no less matters of socio-political construction, as Martijn van der Steen does indeed so argue.[799] In a policy setting, it is crucial to appreciate the importance of positioning within a narrative. One should recall that the HA Report followed the ED Report. Unlike the ED Report, there was a significant duration between the acceptance of the BAC's recommendations in the HA Report and the public announcement of this acceptance. This could to a large extent be attributed to the lack of an adequate narrative and an even greater difficulty in positioning. We discuss this matter further in Chapter 6.

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798 Barbara Vis, *Politics of Risk-taking: Welfare State Reform in Advanced Democracies*. Amsterdam: Amsterdam University Press, 2011, at 125. Representing four possible outcomes as a four-cell grid in applying this reasoning, Vis indicates (at 126-127) that (1) governments will only undertake welfare state reform with risky electoral repercussions if they consider the status quo a loss; (2) if governments pursue reform, the implementation of the reform will be relatively easy if voters are reform-friendly (i.e. if they are also in a losses domain) or relatively difficult if voters are reform-hostile (i.e. if they are in a gains domain); (3) if governments consider the status quo to be a fain, they will not undertake electorally risky reform; and (4) if governments do not favor reform, there will be no conflict if voters consider the status quo as a gain, but conflict may arise if voters consider status quo to be a loss.

799 Martijn van der Steen, Ageing or silvering? Political debate about ageing in the Netherlands, *Science and Public Policy* (October 2008) 35, 8: 575-583, at 578-579.

5.9 Risk and Precaution as Common Fund of Knowledges

How real the risks are was an often and repeatedly asked question throughout the course of the egg donation project. Deborah Lupton describes how the different approaches to analyzing the role of risk in subjectivity and social relations could relate to one another along an epistemological continuum that spans from the realist position at one end to 'strong' constructionist (or relativist) position at the other end.[800] For a realist, risk is an objective hazard, threat or danger that can be measured independently of social and cultural processes, but may be distorted or biased through social and cultural frameworks of interpretation. Key questions that a realist would ask include: What risks exist? How should we manage them? How do people respond cognitively to risks? In contrast, a 'strong' constructionist takes the position that nothing is a risk in itself, since risk is a product of historically, socially and politically contingent 'ways of seeing'. The 'governmentality' and post-structuralist perspectives are stated as reflecting this disposition, and their primary interest is in determining how the discourses and practices around risk operate in the construction of subjectivity and social life. An intermediate position is occupied by a 'weak' constructionist, taking risk as an objective hazard, threat or danger that is inevitably mediated through social and cultural processes and can never be known in isolation from these processes. The ('risk society') approaches of Beck and Giddens, as well as the 'cultural', structuralist and phenomenological perspectives, are indicated as taking this position. However, whereas the 'risk society' approaches would focus on the relationship of risk to the structures and processes of late modernity and its meaning in different sociocultural contexts, the other 'weak' constructivist perspectives consider the choice of certain dangers as risks over

[800] Deborah Lupton, *Risk*. London and New York: Routledge, 1999, at 35.

others, the ways in which risk operates as a symbolic boundary, and the context in which risk is situated.

My understanding, from having interviewed nearly all members of the BAC and HECR Working Group members, is that they tend to share the stance of a 'weak' constructionist. Certain risks, such as the onset of OHSS, and the exploitation of vulnerable groups of women were generally felt to be 'real'. Other risks that are associated with long-term adverse health effects and commercialization are regarded as relatively more value-based or cultural, but no less important or 'real'. More interesting to me is the finding of a relatively prevalent paradoxical attitude towards legal response to these risks. A less directive ethical framework has broadly been considered to be more appropriate than a legal one in the governance of 'emergent' or 'new' technologies. The main reason has been consistently based on the view that scientific and technological progress is faster than law, so that the latter must always (but can never quite) catch up with the former.[801] Such a view considers the law to be always reactive to the risks that have become 'real'. However, a concomitant concern over the efficacy of ethical 'regulation' has contributed to relatively novel legal (and quasi-legal) arrangements that are justified on the ground of precaution. We have considered some of these arrangements in chapter 2 and 3, and here, we consider these developments jurisprudentially.

[801] For instance, Clarence Davis writes: "A regulatory system that takes two years to issue a rule cannot deal with an economy where project lines typically change every six months. A regulatory law focused on types of chemicals cannot deal with something like nanomaterials, where often the same chemical substance can have radically different effects depending on small changes in its shape or the method by which it is manufactured." J. Clarence Davis, Foreword: Nanotechnology, Risk, and Governance. In Christopher J. Bosso (ed), *Governing Uncertainty: Environmental Regulation in the Age of Nanotechnology*. Washington DC and London: RFF Press, 2010, pp xii to xviii, at xvii.

Laurence Boisson de Cahzournes argues that traditional international law reflected a similar reactive approach, in that its application was dependent on the certainty of the imminent occurrence of certain risks (such as risk to international peace and security). However, the precautionary principle or approach, first articulated in the 1992 Rio Declaration on Environment and Development,[802] brought about a new way of engaging with uncertainty. Precaution is a meta-legal principle that allows "legal provisions to incorporate considerations beyond those resulting from strictly positive law."[803] In other words, the precautionary principle recognizes the impossibility of establishing absolute safety, but instead enables action through the determination of four criteria: (1) the 'risk' criterion (encompassing the categories of risks, such as 'unacceptable', 'residual' and 'uncertain' risks, and the components of a precautionary risk assessment), (2) the 'damage' criterion (or impact, which could be severe and irreversible), (3) the 'scientific uncertainty' criterion (generally relating to a minimum level of knowledge), and (4) the 'different capacities' criterion (as states concerned have different capabilities in dealing with a challenge).[804] Apart from these criteria, the values of democracy and transparency are embedded in many international instruments, including the Rio Declaration (in Principle 10), so that public participation is fundamental to the precautionary process.[805] It is important to emphasize here that the four criteria that substantively define precaution and the public engagement with it denote processes that are already encapsulated in organizations and institutions – both national and international. In addition, these processes that embody the

802 United Nations, *Rio Declaration on Environment and Development*, UN Doc. A/CONF.151/26, vol I, annex I, 1992. Paragraph 15 states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

803 Laurence Boisson de Chazournes, New Technologies, the Precautionary Principle, and Public Participation. In Thérèse Murphy (ed), *New Technologies and Human Rights*. Oxford: Oxford University Press, 2009, pp 161-194, at 163.

804 *Ibid*, at 168-178.

805 *Ibid*, at 178-179.

precautionary principle re-balances knowledge systems, such as the interaction between legal politics and science, so that "science would be sought for the suspicions and doubts that it raises rather than for the knowledge it offers."[806]

As a meta-legal principle, precaution has not found uniform application, which suggests the absence of a dominant content that could be broadly imposed. Through an extensive comparative study of policy orientations toward the precautionary principle in the US and in the European Union, Jonathan Wiener found that "from the 1970s through the 1980s, both the United States and Europe adopted precaution in particular laws, and then in international agreements. In the 1990s, Europe – at both the level of the EU and in key Member States – then adopted the PP [Precautionary Principle] as the formal overarching basis for risk regulation, while the United States did not."[807] Despite this difference, the research did not find the US and Europe as growing progressively more precautionary over time. Instead, Europe appeared to be more precautionary in relation to certain risks (such as genetically modified food, toxic chemicals, teenage use of marijuana and other drugs, and guns) whereas the US was more precautionary towards other risks (such as new drug approval and adverse side effects, embryonic stem cell research, cigarette smoking and teenage use of alcohol).[808] These differences were attributable

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806 *Ibid*, at 192.

807 Jonathan Wiener, The Rhetoric of Precaution. In Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. Washington DC and London: RFF Press, 2011, pp 3-35, at 12. The comparative approach combines two comparative methodologies: a set of case studies of specific risks and policies, and a quantitative analysis of a sample of 100 risks drawn from a database of nearly 3,000 risks: see Jonathan Wiener, The Real Pattern of Precaution. In Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe.* Washington DC and London: RFF Press, 2011, pp 519-565, at 524.

808 Jonathan Wiener, The Real Pattern of Precaution. In Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. Washington DC and London: RFF Press, 2011, pp 519-565, at 524-526. Wiener observes (at 526): "Simplistic contrasts – that "Americans are risk-takers while Europeans are risk-averse" – are not supported by actual regulatory experience. Nor are claims that "Americans are individualistic and antiregulation, while

to the occurrence of crisis events, availability heuristics and processes of social amplification, and political responses.[809] As for the general character of risk regulation in the US and Europe, Wiener indicated that neither the case studies nor the quantitative study provided support for the hypotheses of US-Europe convergence, divergence or reversal (flip-flop) in relative precaution over the past four decades.[810] However, the research did show significant interconnectedness and transnational exchange in the diffusion, borrowing and 'hybridization' of regulatory systems.[811]

In addition, precaution is not always referred to in the implementation of risk containment measures. Frances Miller observes that most patient safety initiatives in the US and Europe have not been addressed in precautionary principle terminology. She explains that differences arise mainly owing to events that are largely circumstantial or economic:[812] "under pressure from medical activists for faster access to experimental drugs and from the pharmaceutical industry for accelerated approval policies as the drug industry globalizes, the FDA has relaxed its comparatively rigorous regulatory barriers. At the same time, the EU has increasingly centralized its drug approval processes, tightening the standards in use by some of the less safety-focused Member States, but it has not appreciably raised the level of rigor already in effect in others." Instead, the main risks often associated with biomedical research are risks of physical or psychological harm to participants, risks to the objectivity and scientific integrity of research

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Europeans are collectivist and proregulation," in the face of greater U.S. precaution in regulatory policies that restrict the freedom to smoke and that limit freedom and privacy in order to combat terrorism."

809 *Ibid*, at 540-541.

810 *Ibid*, at 533.

811 *Ibid*, at 541-544.

812 Frances H. Miller, Medical Errors, New Drug Approval, and Patient Safety. In Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. Washington DC and London: RFF Press, 2011, pp 257-284, at 277.

(mainly from conflicts of interests) and risks to other social values, such as public trust.[813] These risks have in turn been scrutinized for potential 'gaps' in 'real world' risk assessment, calibration errors (due to lack of information or multiple variables for instance), different values in risk assessment and evaluation, and different attitudes towards risks.[814] The problem with a strong version of the precautionary principle – as Jonathan Wiener observes – is that it negates other important considerations such as cost, innovation, false positives and risk-risk trade-offs. Instead, the "Better Regulation" initiative,[815] with focus on impact assessment, selection among risks and executive oversight, is regarded as preferable as a more moderate approach for less extreme risks.[816]

Let us return to the paradox we found in public reliance on law and regulation in risks containment, even as the law is considered to lag behind scientific development. Arguably, this reliance amounts in effect to a call for precautionary measures to be adopted. It is hence a call for legal and regulatory processes to make risk explicit by giving it form and substance. For instance, regulatory bodies established through legislation make explicit the types of risk that they attempt to control or ameliorate. In the US, government agencies like the DHHS make apparent a wide range of risks that affect human health and safety, and the environment. More importantly, it is arguably difficult, if not impossible, to understand risks as distinct from legal and other regulatory processes. For 'emerging' areas like nanotechnology, regulatory procedures

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813 Duff R. Waring and Trudo Lemmens, Integrating Values in Risk Analysis of Biomedical Research: The Case for Regulatory and Law Reform. In Law Commission of Canada, *Law and Risk*. Vancouver and Toronto: University of British Columbia Press, 2005, pp 156-200, at 157.

814 *Ibid*, at 160-166.

815 See for instance, the 'Better Regulation' website of the European Commission: http://ec.europa.eu/governance/better_regulation/index_en.htm

816 Jonathan Wiener, The Real Pattern of Precaution. In Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand (eds), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe*. Washington DC and London: RFF Press, 2011, pp 519-565, at 551. Wiener indicates that strong form precautionary principle remains applicable towards extreme catastrophic risks.

have enabled policymakers to manage uncertainty through institutional and regulatory design. Hence the question of what to regulate may not be so different from how to regulate, since the risk envisaged may be indistinguishable from the appropriate regulatory instrument that relates to it.[817] In addition, legal and regulatory rules relate the regulator to the regulated, although this relationship could well be collaborative due to asymmetric information, where the regulated is likely to be far more knowledgeable than the regulator on the 'risks' envisaged.[818] Valverde, Levi and Moore illustrate how legal processes are inherent to understanding the risk of a repeat sexual offence under "Megan's Law", which encompasses the US community notification statutes relating to sexual offenders. Comprising three tiers, this risk assessment process determines the scope of community notification. In examining the constitutional basis of Megan's Law, they observe that "the courts have emphasized the scientific expertise that is said to be behind the registrant risk assessment scale (RRAS) in order to argue that Megan's Law is not a tool of punishment but rather an objective measure to regulate a social problem." However, reliance on Megan's Law as grounded in objective scientific knowledge has given rise to an "intermediary knowledge in which legal actors – prosecutors and judges – are said not only to be more fair but even more reliable and accurate in determining a registrant's risk of re-offence."[819] In this, the study also illustrates a translation from scientific knowledge and processes to legal ones. Taking a position that differs from that of Niklas Luhmann and Gunter Teubner in seeing the 'law' as cognitively and normatively open, Valverde, Levi and Moore highlight that an

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817 Marc Allen Eisner, Institutional Evolution or Intelligent Design? Constructing a Regulatory Regime for Nanotechnology. In Christopher J. Bosso (ed), *Governing Uncertainty: Environmental Regulation in the Age of Nanotechnology*. Washington DC and London: RFF Press, 2010, pp 28-45.

818 Cary Coglianese, Engaging Business in the Regulation of Nanotechnology. In Christopher J. Bosso (ed), *Governing Uncertainty: Environmental Regulation in the Age of Nanotechnology*. Washington DC and London: RFF Press, 2010, pp 46-79.

819 Mariana Valverde, Ron Levi and Dawn Moore, Legal Knowledges of Risk. In Law Commission of Canada, *Law and Risk*. Vancouver and Toronto: University of British Columbia Press, 2005, pp 86-120, at 103 and 106.

institutional or structural arrangement like the court may enable the creation of a "more or less common fund of knowledges" by which conceptions of 'risks' materialize:[820]

> [I]t is important to note that the swapping of knowledge is not simply a result of one-time social interactions between actors with different training. The swapping is built into the very structure of the court. In an interview, the judge explained that he is not himself an expert on addiction. Rather, the team structure of the court…allows everyone in the court to use the same knowledges…The use of the term "team" is quite purposeful since it erases the institutional distinctions that would in other situations not only divide people but set them at cross-purposes.

We conclude by reiterating that the notion of risks is essentially anticipatory,[821] and it requires a precautionary response – of being prepared – that in turn necessitates recourse to this 'common fund of knowledges'. In contemporary societies, Andrew Lakoff and Stephen Collier illustrate how the vulnerability of critical infrastructure (such as water, electricity, communication and transportation) has become an object of knowledge for security experts in the US. Threats that include natural disasters, terrorist attacks, technical malfunction and novel pathogens not only endanger infrastructure, but also, collective life which it enables and sustains. Consistent with our considerations so far, it is the responses to these threats (or risks) that relate more directly to knowledge production than the object itself. This is arguably all the more so, where the 'object' of knowledge is not something tangible, but a consortium of societal ideals. We have also noted

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820 *Ibid*, at 115. Luhmann and Teubner are said to conceptualize the law as "cognitively open but is normatively closed" (at 94).

821 We conclude by working through an analytical framework put forward by Nelson, Geltzer and Hilgartner: Nicole Nelson, Anna Geltzer and Stephen Hilgartner, Introduction: the anticipatory state: making policy-relevant knowledge about the future, *Science and Public Policy* (October 2008) 35, 8: 546-550, at 547.

that many of these risks are anticipatory (or precautionary) in that they have yet to materialize (for indeed, we do not have chimeric humanoids in our midst), but they are made 'real' mainly through the imaginative enactment of certain types of events, or through what Lakoff and Collier refer to as a "political technology of preparedness". These responses or interventions have epistemological basis when applied to a problem of collective life and could be regarded as knowledge systems to varying degrees.[822]

In anticipating the progress of human embryonic stem cell research, the ED report provides a pre-emptive account of the possible health and ethical risks that could arise.[823] Health risks have been articulated and accepted on a basis of institutionalized trust in the formulations of the US NAS (and primarily the NRC and IOM), and subsequently generalized by the IRGC. Ethical (and 'unquantifiable') risks appear to have a more indigenous character, but have not been any less individualizing in effect. Through a 'white-washing' process, the BAC has limited individualization through the construction of a civic epistemology that is anticipatory and precautionary. Policy-makers have since relied on precaution in decision-making, agenda-setting and legitimation. It is also a means by which plurality of futures are managed. However, the extent that this civic epistemology is consistent with democratic ideals is unclear. The common assumption is that the BAC has (like the state) prioritized economic potentials and interests over other values and ends. In the next chapter, we consider the impact of a narrative of gain, rather than one of loss.

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822 Andrew Lakoff and Stephen J. Collier, Infrastructure and Event: The Political Technology of Preparedness. In Bruce Braun and Sarah J. Whatmore (eds), *Political Matter: Technoscience, Democracy, and Public Life*. Minneapolis and London: University of Minnesota Press, 2010, pp 243-266, at 244. Lakoff and Collier illustrate how institutionalized knowledge was developed in the United States Civil Defense in the 1950's as a form of vulnerability mapping in the event of a surprise nuclear attack by the Soviet Union (at 249-255).

823 As we have seen in the earlier chapters, the involvement of the PES suggests that there were political risks. However, it is difficult to distinguish this clearly from ethical risks. For ease of discussion, ethical risks are taken to encompass political risks as well.

CHAPTER 6

JURIDIFICATION AND REGULATIONISM IN GOVERNMENTALITY: RE-EMERGENCE OF THE STATE

Abstract

Under the mandate of examining 'ethical, legal and social implications' of research involving human-animal combinations, the BAC has applied legal reasoning, norms, practices and techniques in co-producing and sustaining epistemic claims and 'things'. I refer to this hybridization of the 'legal' with other modalities of power as juridification within a power-complex originally proposed by Foucault as governmentality. Whereas a narrow reading of governmentality suggests the sequestration of state (or sovereign) power by disciplinary (and bio-) powers or otherwise the subsumption of law into ethics, this research supports an alternative reading, which suggests a more productive and open-ended relationship between law and disciplinary powers, including science. To understand the nuances of this power complex, I have applied ANT to explicate particular network configurations of power modalities and their interactive spaces. By so deploying this mode of inquiry, I attempt to present an analytic as 'regulationism'. Applying this analytic to my ethnographic subject, I argue that the law remains central to our experience of modernity in the pseudo-juridical nature and work of the BAC, thereby also re-casting Foucaldian conceptions of 'law' and 'state'.

6.1 The Story So Far

The HA Report and its recommendations were officially made public at a press conference held on 22 September 2010. This seventh report of the BAC was published after an embargo of almost a year from the time it was accepted by the SCLS. A reason for this delay is the lack of clarity as to which government agency should assume regulatory responsibility over research involving human-animal combinations. Another concern was over possibly adverse and aggressive public reaction towards the government's endorsement of the research, especially by a number of vocal religious groups. A contact mentioned that this concern was especially pertinent as Singapore's 16th Parliamentary general election was expected to take place soon (the election took place some time later, on 7 May 2011).[824] To allay this worry, a copy of the report was sent ahead of the press conference to leaders of the main religious groups, with an invitation to meet with the BAC on 15 September 2010. The purpose of this meeting was to explain the BAC's position, which differed from that of some religious viewpoints largely due to fundamental disagreements over the ethics of human embryonic stem cell research. While the BAC did not anticipate any new grounds of concerns to be raised, it did not rule out the option of a further delay to the public release of its recommendations should this meeting turn out badly.

The meeting did not ultimately draw many religious group leaders, although representatives from the most active respondents during the public consultation (ie National Council of Churches in Singapore (NCCS), the Catholic Medical Guild and the Islamic Religious Council of Singapore (MUIS)) were present. The experience at this meeting did not differ from a previous meeting, also with religious group leaders, on 13 September 2008, where the same representative from

[824] Interview (MT), 3 March 2010.

NCCS was critical that the BAC did not respond sufficiently to the ethical concerns that were raised by the religious groups. This representative appeared to be more reconciliatory at this meeting, but reiterated his organization's objection to the research. The presence of representatives from MUIS was important as it was not fundamentally opposed to the research, provided that certain (mainly regulatory) safeguards were met. This difference in religious viewpoint appeared to have an effect in shifting the attention to more pragmatic (as opposed to dogmatic) concerns. The meeting itself appeared to validate the experiences of CIRM on the importance of public engagement. In my interviews with Professor Bernard Lo and Dr Geoffrey Lomax,[825] both of them emphasized the importance of engaging with the public even though the CIRM need not accept all the comments from the public. They indicated that it was important to respond to comments from the public, and where applicable, explain why the CIRM has adopted a different viewpoint or stance, or the reasons for its disagreement with public opinion. Professor Lo felt that this practice has been effective in engaging the public, and in helping the public understand and accept why certain policies were formulated in a particular way even if they did not agree.

Given the relatively calm reception by the religious group leaders of the recommendations, the BAC went ahead with their scheduled release. The Press Conference was attended by reporters from local newspapers and a regional news agency. No foreign press was present even though invitations have been sent to them. This was unlike the release of the BAC's recommendations for human embryonic stem cell research in 2002, when media hype on the subject was at a peak, or the release of its recommendations on genetic testing in 2005, around the time when news of the scandal in South Korea broke out. In its press release, the BAC highlighted that its

[825] Interview with Professor Bernard Lo (on 16 August 2008) and Dr. Geoffrey Lomax (on 12 May 2009).

deliberation on research involving human-animal combinations was motivated by a desire to "update its recommendations for human stem cell research, especially in the light of recent developments", and it further reiterated that it "expects stem cell research to have considerable potential in the treatment of currently incurable diseases", also noting that "[c]linical trials of stem cell treatments are beginning in a number of countries."[826] These points were captured in the press reports that followed; all of which consistently stating public concern over possible breach of perceived differences between humans and animals, the benefits that could be derived from stem cell science and technology, as well as the ability to circumvent ethical challenges and to harness the benefits through reliance on sound and effective regulation by a national body on stem cell research.[827] Similar sentiments were articulated by the then-Minister for Health Mr Khaw Boon Wan (now Minister for National Development), who wrote on his blog that rational assessment is needed in considering how to move forward with the technology:[828]

> I remember the movie, "The Fly", in which a research project went awry and the scientist involved acquired fly-like capabilities and yucky eating habits. He tried desperately to reverse the experiment but never succeeded. It was a popular movie theme and "The Fly"

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826 Bioethics Advisory Committee, *Press Release: Human-Animal Combinations in Stem Cell Research*, 22 September 2010, at paragraph 4.

827 Claire Huang Jingyi, Bioethics advisory panel proposes national body to monitor stem-cell research: one of 5 recommendations following 2-year consultation exercise, *TODAY*, 23 September 2010; BAC recommends setting up a body to monitor stem cell research, *Channel News Asia*, 22 September 2010 (available at: D:\1 HECR Project\2010-09-22 - Release of HAC Report\2010-09-22 - Press Conference\News Reports\2010-09-22 - CNA - BAC recommends setting up a body to monitor SC research.mht); Grace Chua, Call for national body on stem cell research: It should review research involving human-animal combination of cells, *The Straits Times*, 23 September 2010; Xu Xiang Yu, Mouse with Consciousness, Pig with Feelings: Human-Animal Combinations; There will be Chaos in the World, *Joint Evening Newspaper*, 22 September 2010; Chua Huiling, Bioethics Advisory Committee: Establish National Body to Control Human-Animal Stem Cell Research, *Joint Morning Newspaper*, 23 September 2010; Oleh Samshul Jangarodin, Penubuhan badan semak dan pantau kerja penyelidikan sel induk disaran [Proposed establishment of monitoring body for stem cell research], *Berita Harian* [Daily News], 23 September 2010.

828 Blog posted by Ministry of Health on 23 September 2010, and subsequently reported in The Straits Times: Allow for genuine research, leave out the yucky stuff, 24 September 2010.

> was remade by different Directors. I have at least watched two different versions of it. Scientists will want to push the boundary, to discover, to invent, to benefit mankind. Rogue scientists are rare and we need rules to rein them in, without stifling genuine research with good potential. The easiest thing, as a regulator, is to say "No" to all such pursuits. But we will be missing out on opportunities that can benefit us all. In any case, sweeping things under the carpet does not prevent rogue scientists from pushing the boundary in perverse ways…MOH is studying their recommendations and will respond to them. Personally, I find the proposed BAC approach practical: allow some research, but limit it to a narrow area where the potential for benefits is significant and real, and regulate such research tightly. As for the potentially yucky stuff, continue to prohibit it.

Several days later, the MOH announced its formal acceptance of the BAC's recommendations, adding that it was in the process of drafting a new legislation to regulate research involving cytoplasmic hybrids and the introduction of human pluripotent stem cells into animals. In addition, the MOH indicated that it will work with the Ministry of National Development and the AVA to establish a "robust framework to ensure compliance with BAC's recommendations".[829]

Interestingly, the recommendations of the BAC did not appear to be correctly understood by the AVA at the initial stages. The AVA issued a circular on 1 October 2010 wherein it indicated that it would strongly advise that the Institutional Animal Care and Use Committee (IACUC) should not approve research involving the creation of cytoplasmic hybrid embryos and the introduction of human stem cells into animals until such time when the BAC's recommendations are

[829] Ministry of Health, *Press Release: MOH accepts Bioethics Advisory Committee's recommendations on Human-Animal Combinations in Stem Cell Research*, 27 September 2010.

implemented.[830] This was a surprising occurrence as it is explicitly provided in the BAC's report that existing arrangements relating to the IACUC to ensure the welfare of lab animal should continue to apply, particularly where there is no serious risk of the research animal developing human sentience or consciousness. As a consequence of the circular, researchers have sought clarification from the AVA as to whether multipotent stem cells fall within the ambit of the BAC's recommendations. The AVA in turn contacted the BAC for clarification. In relation to the creation of cytoplasmic hybrid embryos, no mechanism was as yet in place for research approval to be granted. As such, cybrid research could not be conducted in Singapore until the proposed regulatory framework is in place. However, there was less concern here as there did not appear to be any urgency among researchers in conducting this research.

In clarification, the BAC explained that it would not see the use of multipotent stem cells in nude mice as creating any ethical difficulties or need for special provision. It is already common practice to use mice as the means for testing human stem cells. In addition, it reiterated (with reference to paragraph 4.11 of the HAC Report) that it envisaged separate and non-overlapping reviews by AVA (focused on animal welfare) and institutional IRB (focused on the ethics of stem cell research). Therefore, the BAC has no objection to the use of laboratory strains of mice specifically developed for laboratory research (such as nude mice) with human stem cells of any kind. This research was not considered to raise any new issues for animal welfare, since the injection of human stem cells into mice for test purposes is routine laboratory practice. Following this communication, the AVA reinstated the status quo through the issuance of a follow-on clarification circular.

[830] Fieldnotes (including communication with Dr. Lim Bing), 30 October 2010.

This episode involving the AVA, MOH and the BAC illustrates a particular network of power that animates the 'state' or 'government' in the context of biomedical research. There are divergent interests and responsibilities, most directly represented by the different ministries that constitute this network. In addition, there are advisory bodies and coordinating agencies that are usually not adequately accounted for. For highly technical areas like policies on human embryonic stem cell research, the 'government' did not present itself in the form of a paternalistic, all-knowing and repressive developmental state. This does not imply an absence of political agenda or coercive power, but the relationship between the different modalities of power is a dynamic one. We find agency to be reposited in different localities within, as well as along the boundaries of, inter-relational power and knowledge structures. More importantly, the BAC became the assemblage point or outlet in terms of policy actions. At this stage (and akin to an adjudicative structure), the reliability of state power has become so convincing that the action of the AVA was sufficiently de-politicized, so that neither the religious group representatives (some of whom remain opposed to the research) nor members of press appeared to be particularly perturbed. In other words, the BAC and its regulatory regime appear to have gained recognition as implementing a system of governance. Although 'private' in form, this system is intricately linked to state power and (as we shall see) the legal system. In the sections that follow, we first consider the critical role that state power continues to have in re-thinking the Foucauldian notion of 'governmentality' in biomedical research. Due to a variety of reasons that include requirements of 'good science' (Chapter 1), institutional relationships (Chapters 2 to 4), and notions of 'risk' and 'precaution' (Chapter 5), state action is now (inter-)mediated by other modalities of power in a particular network configuration that I refer to as regulationism (discussed below). Juridification as persistence of state (and juridical) power, and effected

through regulationism, imbues in bioethics a power-complex that is more open-ended and contestable, but intricately and ultimately centered around the state.

6.2 The Innovative State

In the previous chapter, we have considered the constitutive power of risk discourses. Perceptions of risk have been a ground of sociality, and a legitimizing force for policy decisions that shape social arrangements. To the extent that the recommendations of the BAC address risk concerns, its work could be considered to be an intricate part of a broader political technology of preparedness. As we have considered, 'risks' have operated in various forms and at different levels to motivate and justify policy development. In this section, we broaden our consideration to the non-consequentialist character of 'risks'. In particular, we consider their affective qualities that appeal to solidarity (or 'communities of fate', as will be discussed below). These are arguably the qualities that secure durability in socio-political arrangements, beyond purely utilitarian calculations. By linking life sciences initiatives to the long term survival prospect of Singapore, bioethics has become a *raison d'être* for (as well as, of) government. As a tiny nation-state, policy-makers have been especially conscious of Singapore's vulnerability. The trauma of expulsion from the federation of Malaysia in the short space of about two years of achieving independence from colonial rule may have further etched this vulnerability into the national psyche. Not surprisingly, a journalist asked Lee Kuan Yew (the architect of modern

Singapore) in a recent interview if the nation-state should be "always living in fear of a catastrophe".[831]

Through what has been described as a developmental state model, the state-led industrialization of Singapore between the late 1960's to 1990's capitalized on the nation state's locational and infrastructural strengths to attract transnational corporations. This strategy has been relatively successful in enabling Singapore's capabilities in back-end manufacturing, consumer electronics and a variety of financial and distributional services, which have in turn generated economic returns and a crucial source of legitimacy for the state. The rule of law has often been regarded as intrinsic to this developmental strategy. The assurance that the state will 'stick to the law' has been considered to be critical in securing stable relations with transnational corporations and ensuring continued foreign direct investment. By this formulation, the rule of law amounts in effect to the security of persons, property rights and contract enforcement. Such a conception of law could be traced to Friedrich Hayek, whose preference for a minimal state has attributed to the Common Law a spontaneous (rather than engineered) origin and a prioritization of the rule of law ahead of development. Reflecting on the development experiences of East Asian nations, Francis Fukuyama takes a different view in arguing that the rule of law is but a distinct dimension of development, and not a precondition.[832] Referring to the industrialization of South Korea between 1954 and 1990, he observes that state building has led to economic growth, and economic prosperity has led to rule of law, greater legitimacy of the state and social mobilization

831 Han Fook Kwang, Zuraidah Ibrahim, Chua Mui Hoong, Lydia Lim, Ignatius Low, Rachel Lin and Robin Chan, *Lee Kuan Yew: Hard Truths to Keep Singapore Going*. Singapore: Straits Times Press, 2011, at 25.

832 Francis Fukuyama, *The Origins of Political Order: From Prehuman Times to the French Revolution*. New York: Farrar, Straus and Giroux, 2011, at 470.

in terms of people forming interest groups in civil society thereby gaining access to politics.[833] However, state building does not necessarily lead to the development of the rule of law. Fukuyama notes that while China was among the first to have adopted state building, it failed to develop rule of law and political accountability. However, this legacy of state building was a basis for highly-qualified authoritarian governments, as exemplified in successful authoritarian modernizers including South Korea, Taiwan, Singapore and modern China itself. The success of these countries is attributable not so much to political institutions, but to cultural commitment towards science, learning and innovation. Consequently, economic success has been achieved even though the rule of law and political accountability are relatively underdeveloped in many East Asian countries.[834]

To be sure, Fukuyama's point is *not* that the rule of law is unimportant. Effective legal institutions are difficult to construct as they require physical facilities and huge investments in the training of lawyers, judges and other officers of the court, including law enforcement officers.[835] When developed, the rule of law is an important component of political order that enables political accountability, and this in turn provides a peaceful path toward institutional adaptation.[836] Fukuyama's observation that is of importance to our discussion here is that the state must intentionally and systematically adopt the rule of law. This is perhaps most evident in his argument that the Common Law was intimately associated with the rise of the early English

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833 *Ibid*, at 474-475. Fukuyama observes (at 473) that the governments of Singapore and Malaysia have been able to maintain popular support despite of lack of liberal democracy due to rapid economic growth, which has served to legitimize government policies. In contrast, the Indonesian state lost legitimacy when its economic growth faltered during the financial crisis of 1997 to 1998.

834 *Ibid*, at 317.

835 *Ibid*, at 247.

836 *Ibid*, at 482-3.

state and dependent on state power for its eventual dominance.[837] To understand biotechnology in Asia, Aihwa Ong emphasizes the need to take the role of the state seriously. Within an analytic of global assemblages, she argues that the notions of the state, its people and their collective interests are re-created in biotechnologies:[838]

> Contrary to popular perceptions, the regulation of biotech flows is managed not only by pharmaceutical companies and global health agencies, but also by nationalist states that increasingly shape and patrol flows of human tissues and biotech products. In contrast to market-state systems, emergent players in the field of biotechnology and biomedicine are situated in political environments with robust sovereignty and paternalist rule. Having laid the foundation for capitalist development, Asian states are turning to biotechnologies as a mechanism of regeneration, not only of the economy and of the people, but also of national prestige.

Different forms of biotechnology have been used to generate and influence corporeal and affective interests, or "communities of fate", which refers "not to elements of a global civil society but to the network of collectivities that become connected as a result of diverse ethical decisions and feelings associated with technological innovations."[839] Taken together, Ong sets out "Asian biotech" as referring to "an assemblage of science, politics, and collective concerns

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837 *Ibid*, at 253, 256-257. Fukuyama observes that the early monarchs like William I and Henry I had an interest in acting as a court of appeals in cases where subjects were not satisfied with the justice dispensed by the local seigeurial or manor courts. The monarchy earned a fee for services relating to dispensation of justice, and this further increased the prestige of the king, and in turn undermined the authority of local lord when his opinion was overturned.

838 Aihwa Ong, An Analytics of Biotechnology and Ethics at Multiple Scales. In Aihwa Ong and Nancy N Chen (eds), *Asian Biotech: Ethics and Communities of Fate*. Durham and London: Duke University Press, 2010, pp 1-51, at 15-16.

839 *Ibid*, at 20.

that configures a realm of transcendent imaginary in which sciences in tandem with ethics shape political identities."[840] Of especial pertinence to us is the anthropology of 'situated ethics' that Ong puts forward. As she explains, this notion "rejects the common assumption that moral reasoning can be simply determined by class location, or reduced to the scale of the isolated individual... [Instead,] it is more fruitful to locate moral reasoning at the intersection of overlapping scales of risk and ethics."[841] As in South Korea and Japan, policymakers in Singapore have deployed regenerative medicines as apparatus of biosecurity in the production of "a new idiom of ethics that is bringing to life communities of shared corporeal needs and vulnerabilities. Biotech and biomedical procedures thus trigger emotional maps of belonging and collective fate, enhancing an awareness of the scientific and raising the security stakes of being modern Asian subjects."[842] Through this observation, Ong argues that 'communities of fate' combines the rationalities of market and science with the 'irrationalities' of feeling and identity in a manner that displaces a strict binary of nature versus culture.

Many scholars have pointed to a distinctive openness to Singapore's approach. Together with Hong Kong, William Keller and Richard Samuels label this 'technoglobalist' given the nation-state's subscription to a political philosophy of free trade within an open international economy with unfettered capital mobility and a relatively laissez-faire regulatory system.[843] In contrast, the approaches of Japan and South Korea are regarded as 'technonationalism' under this schema, as

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840 *Ibid*, at 21. Ong (at 43) generalizes "Asia" as "a region of political and ethical contradictions, of population surplus and bio-insecurity, of economic backwardness and full-throttle capitalism, of memories of colonial humiliations and the cumulative force of resurgent nationalism".

841 *Ibid*, at 34.

842 *Ibid*, at 34-35.

843 William W Keller and Richard J Samuels, Innovation and the Asian economies. In William W Keller and Richard J Samuels (eds), *Crisis and Innovation in Asian Technology*. Cambridge: Cambridge University Press, 2003, pp 1-22, at 11. Keller and Samuels recognize that their ideal-typical schema does not provide a complete (and possibly inaccurate) portrayal of the technological regimes in East Asian countries, but their explicit goal is to put forward states as the primary units of analysis.

there have been stronger tendencies to exert domestic control over production processes and less reliance on foreign direct investment.[844] Taiwan falls in between the two groups, in an approach that represents 'technohybridity'.[845] Charis Thompson similarly observes Singapore's strategy to be 'internationalist', with policies that include the "serial kidnapping" of leading biomedical researchers from around the world to further its nationalistic goals.[846] Her ethnographic study that compares Singapore with South Korea clearly distinguishes the two regimes:[847]

> Singapore built and began to fill a facility devoted to a lifestyle of integrated research that embodied both the bench-to-bedside trajectory and the convergence of business, information, and biosciences, while taking care of all the living needs of its civic entrepreneurs. [Referring to South Korea's Dr Hwang Woo Suk before his fall from grace] The prize of one was, or could have been glory…[Referring to Singapore] The prize of the other is its potential to be Asia's, if not the "world's easiest place to do business," thanks to its stable legal, political, and economic environment. While Singapore has led the way in regional intellectual property law and finance reform, South Korea has been urged by the European Union and others to strengthen its intellectual property regimes. While Singapore continues to pay foreign faculty more than its nationals and to recruit superstars from prestigious universities overseas, South Korea saw one of its own nationals become a household name around the world, and boasts the

844 *Ibid*, at 10.

845 *Ibid*, at 12. This categorization has found some degree of support in a recent ethnographic study: Jennifer Liu, Asian Regeneration? Technohybridity in Taiwan's biotech? *East Asian Science Technology and Society International Journal* (2012) 6, 3: 401-414.

846 Charis Thompson, Asian Regeneration? Nationalism and Internationalism in Stem Cell Research in South Korea and Singapore. In Aihwa Ong and Nancy N Chen (eds), *Asian Biotech: Ethics and Communities of Fate*. Durham and London: Duke University Press, 2010, pp 95-117, at 112.

847 *Ibid*, at 113-114.

most successful education system in the world. Both represent different ways of being Asian Tigers.

Joseph Wong attributes Singapore's 'internationalism' to its historical linkages with multinational firms, including big pharmaceutical companies, as well as its locational advantages.[848] However, he is correct in observing that investment in biotechnology involves 'different kinds of bets', in view of uncertainties as to technological viability, economic (and, particularly commercial) value, and temporal range (as the "distance between laboratory and market continues to be very long, unpredictable, and fraught with unforeseeable snags along the way, including regulatory constraints, clinical obstacles, and market uncertainties").[849] More importantly, Singapore (like Taiwan and South Korea) recognizes its own vulnerabilities, particularly its small economy and lack of experience with the development and commercialization of technological innovation.[850] But what this ethnographic study has found is that the state has not retreated into obscurity, but has adapted its policy strategies to address and manage the uncertainties in the life sciences. This is a development that is inconsistent with neoliberalism, which puts forward the view that it is in the public interest to reduce government intervention and allow the operation of the market to benefit as many 'consumers' as possible.[851]

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848 Joseph Wong, *Betting on Biotech: Innovation and the Limits of Asia's Developmental State*. Ithaca and London: Cornell University Press, 2011, at 2.

849 *Ibid*, at 7.

850 Wong observes: "Like most other advanced economies, Korea, Taiwan, and Singapore are rich but relatively small, so their prospects in commercializing biotech will depend on global markets, investment, and R&D collaboration. Like many others, they are late entrants into the life sciences field, and relatively inexperienced. They are also without the scale advantages we see in the United States, and emerging giants such as China and India. As a result, decision makers in these three economies, like those in other places, must make strategic choices about how to allocate resources, coordinate disparate actors, and manage the uncertainties of long-term biotech innovation." *Ibid*, at 15.

851 Warwick Funnell, Robert Jupe and Jane Andrew, *In Government We Trust: Market Failure and the Delusions of Privatisation*. London: Pluto Press, 2009, at 17. Neoliberal thinking was traced to the 1970s when liberal democracies abruptly turned away from what was perceived to be the unchecked growth of the welfare state to public sector reform that forced the retreat of government from the provision of social services. This

A neoliberal agenda directed at creating a 'market society' could lead to a failure of public life,[852] and is not necessarily consistent with the ideals of democratic society.[853] To be sure, neoliberal thinking has been extremely influential on policymakers here, and this has contributed to the privatization of many state-owned enterprises in education, health and other public services from the 1990's. Yet, a critical policy feature has been the ability of the state to channel private initiatives into areas of state priority, and to structure and use state power for development.[854]

An important observation advanced by Wong, and consistent with my ethnographic study, is the emergence of a "multiple stakeholder state", responsible for promoting research and development on the one hand, but also for the protection of human subjects that are involved in research on the other.[855] As these competing goals immediately make clear, regulatory policies are contested among different actors, including within government by different ministerial interests, and consequently uncertain. The state itself has multiple roles, as a mediator and broker, having to reconcile these competing interests, values and perspectives. The inherent uncertainties of regulatory policies relating to the life sciences, and the challenges of asymmetric information, limit the ability of the state to impose a single viewpoint or regulatory stance. Apart

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phenomenon may be further attributed to the inability of Keynesian economics to deal with the 'stagflation' of the 1970s (at 12-16).

852 Anthony Giddens, *The Third Way and its Critics*. Cambridge: Polity Press, 2000, at 51.

853 Funnell, Jupe and Andrew I think correctly observe that concern over the ability of public servants to influence resource allocation decisions in ways that are detrimental to public interests is not necessarily addressed by re-assigning such decisions to the market, for instance. Warwick Funnell, Robert Jupe and Jane Andrew, *In Government We Trust: Market Failure and the Delusions of Privatisation*. London: Pluto Press, 2009, at 273-274.

854 Atul Kohli's comparative analysis of the state as an economic actor in developing countries is helpful in highlighting the "*key issue…[as] how elites structure use state power for development…power to define goals clearly and narrowly and power to pursue those goals effectively*." Atul Kohli, *State-Directed Development: Political Power and Industrialization in the Global Periphery*. New York: Cambridge University Press, 2004, at 385-386 (Emphasis added). See also pp 10-12.

855 Joseph Wong, *Betting on Biotech: Innovation and the Limits of Asia's Developmental State*. Ithaca and London: Cornell University Press, 2011, at 148-150.

from brokerage and mediation, the state further functions as both a market and premarket regulatory gatekeeper, especially because the biotech and healthcare sectors "are not constituted solely by consumer demand and industry supply…[but] by the regulatory functions of the state that shape market access for biotechnological innovations."[856] In addition, the state, as the monopsonistic purchaser of care also affects in some way the price of all health care products and services.[857] Putting this more generally, the state not only defines the regulatory space, but could deploy science and technology as regulatory tools to further social and political goals.[858] Link and Link goes further to argue that the government has been and should act as entrepreneur in the provision of technology infrastructure when its involvement is both innovative and characterized by entrepreneurial risk. In the context of the US, they highlight six policy action frameworks, and using a nonlinear model of innovation, show how positive impact has been created when the government acted as entrepreneur on the economy and on society.[859] Specific examples of the US government having acted as entrepreneur, primarily through public-private partnerships, include establishing research joint ventures, the National Institute of Standards and Technology, and university research parks.[860] The above discussion makes clear that, contrary to neoliberal thinking of a limited state, the generation of corporeal and affective interests, or 'communities of fate', and the management of uncertainties are some of the rationales for a more

856 *Ibid*, at 156, and 151.

857 *Ibid*, at 158.

858 Roger Brownsword and Karen Yeung, Regulating Technologies: Tools, Targets and Thematics. In Roger Brownsword and Karen Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes*. Oxford and Portland: Hart Publishing, 2008, pp 3-22, at 8-9.

859 The six frameworks are set out as National Cooperative Research Act of 1984, the Omnibus Trade and Competitiveness Act of 1988, the Organic Act of 1901, the Biomass Research and Development Act of 2000 as amended by the Food, Conservation, and Energy Act of 2008, the Building a Stronger America Act (pending) and the Small Business Innovation Development Act of 1982. Each of these resulted in a public/private partnership that had the economic objective of leveraging either public-sector R&D or private sector R&D, or both. Albert N. Link and Jamie R. Link, *Government as Entrepreneur*. New York: Oxford University Press, 2009, at 157.

860 *Ibid*, at 158-160.

meaningful and engaging state presence. In specific situations and conditions, it is at times less clear if state involvement amounts to control or empowerment.

6.3 Re-thinking the Law in Governmentality as Co-Production

In *Discipline and Punish*, Michel Foucault characterizes law as the embodiment of sovereign power, or essentially as orders backed by threats. With the rise of disciplinary power, Foucault considers that the sovereign and its power (ie law) must necessarily weaken. As society increases in complexity, the old order of law would ultimately be expulsed by the new order of disciplinary powers.[861] For this reason, Foucault states that if there should be a struggle against disciplines or disciplinary powers, our recourse should be to nondisciplinary power rather than to the old right of sovereignty.[862] This limited notion of law has been most thoroughly critiqued by Alan Hunt and Gary Wickham. They observe that, like John Austin before him, Foucault has inflexibly linked law to the sovereign. Law is thereby reduced to criminal law, with the omission of other aspects of law that relate to broader social phenomena and the distribution of social authority.[863] They argue that law has always been involved in, if not preoccupied with, the task of either exercising control over or exempting from control the different forms of disciplinary regulation. Contrary to Foucault's claim that disciplinary power is of relatively recent origin, Hunt and Wickham point out that ethical and processual (or ritualistic) discipline and law were

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861 Michel Foucault, *Discipline and Punish: The Birth of the Prison* (translated by Alan Sheridan). New York: Vintage, 1995, at Parts I and II.

862 Michel Foucault, *'Society Must Be Defended': Lectures at the Collège de France, 1975-76* (translated by David Macey). London: Allen Lane, 2003, at 39-40.

863 Alan Hunt and Gary Wickham, *Foucault and Law: Towards a Sociology of Law as Governance.* Pluto Press: Finland, 1994, at 60. The authors recognise that law is not Foucault's primary object of concern, although his ultimate interest on the development of a 'punitive rationality' and its implications on freedom have a profound relationship with the question of law.

intrinsic to the rationale of state. In addition, Foucault's dialectic approach of setting law against discipline (or 'counter-law') fails to recognize that both forces are concerned with governmentality. They explain that governmentality is the dramatic expansion in the scope of government, featuring an increase in the number and size of the governmental calculation mechanisms, as well as modern bureaucracies. This expansion occurred at about the same time as a number of other themes, including the emergence of the reason of state, the emergence of the problem of population, the birth of modern political economy, the move towards liberal securitization, and the emergence of the human sciences as new mechanisms of calculation. In particular, it is the reason of state that requires the government to decipher the mystery of the state and calculate the correct principles for its ordering.[864]

Foucault's negative framing of (positive sanction-based) law appears more ambivalent in his later works.[865] In differentiating bio-power as applicable to populations in contrast to disciplinary power that individualizes bodies, he seems to recognize that it could perhaps be too simplistic to regard government as concerned only with control or domination.[866] The state must necessarily draw on both its sovereign power, as well as disciplinary (and bio-) powers in order to maximize the capabilities and wellbeing of its population. While alluding to the interaction between old and new forms of power, he continues to point to juridical regression, although accepting the

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[864] *Ibid*, at 76.

[865] The negative framing of law (as opposed to the more 'productive' discipline) is perhaps most evident in his discussion on Power/Knowledge. See Michel Foucault, *Power/Knowledge: Selected Interviews and Other Writings 1972-1977* (translated by Colin Gordon et al.). Brighton: Harvester Press, 1980, at 119, 122 and 139.

[866] Even then, Foucault continues to regard discipline and law to be incompatible or competing: Michel Foucault, *The Will to Knowledge: The History of Sexuality, Vol. 1* (translated by Robert Hurley). Harmondsworth: Penguin, 1979, at 97; 137-139. See also Michel Foucault (translated by David Macey), *'Society Must Be Defended': Lectures at the Collège de France, 1975-76*. London: Allen Lane, 2003, at 38-39.

increasing importance of law as norm.[867] However, Foucault appears to have provided his most positive affirmation of state law in his discussion of governmentality as a new power-complex of the modern state. This notion relates to an "ensemble formed by the institutions, procedures, analyses and reflections, the calculations and tactics, that allow the exercise of this very specific albeit complex form of power…"[868] Of its three components, he describes one as "the ensemble formed by institutions, procedures, analyses and reflections, calculations, and tactics that allow the exercise of this very specific, albeit very complex, power that has the population as its target, political economy as its major form of knowledge, and apparatuses of security as its essential technical instruments."[869] Far from expulsion, sovereign law remains an integral (albeit hybridized) part of a triangulation of law, disciplines and administration, as Rose, Valverde and others have read Foucault.[870]

At an analytical level of narrowly understanding law to be 'orders backed by threat', my research supports this latter reading of Foucault in that institutions of law and law enforcement remain very much an intrinsic part of the governmentality of biomedical research. As we have seen, the work of the BAC must be understood in terms of its ongoing interactions with other governmental agencies (for instance, the MOH and AVA) and with the disciplines of ethics, science and medicine, among others. The development of a rationality of state encompasses not

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867 Michel Foucault, *The Will to Knowledge: The History of Sexuality, Vol. 1* (translated by Robert Hurley). Harmondsworth: Penguin, 1979, at 144.

868 Michel Foucault, Ethics: Subjectivity and Truth. In Paul Rabinow (ed.), *Essential Works of Michel Foucault, 1954-1984.* The New Press: New Press: 1997, at 20.

869 Michel Foucault, Governmentality. In Graham Burchell, Colin Gordon and Peter Miller (eds), *The Foucault Effect: Studies in Governmentality*. Hertfordshire: Harvester Wheatsheaf, 1991, pp 87-104, at 102. Foucault explains: "We need to see things not in terms of the replacement of a society of sovereign by a disciplinary society and the subsequent replacement of a disciplinary society by a society of government; in reality one has a triangle, sovereignty-discipline-government…": *Ibid.*

870 Nikolas Rose and Mariana Valverde, Governed by Law? (1998) *Social and Legal Studies* 7: 541-51; Anthony Beck, Foucault and Law: The Collapse of Law's Empire (1996) *Oxford Journal of Legal Studies* 16: 489-502; Duncan Ivison, The Technical and the Political: Discourses of Race, Reasons of State (1998) *Social and Legal Studies* 7:589-94.

only 'punitive rationality,' which Foucault equates as law, but also disciplinary power, encapsulated in rituals, processes, techniques and norms that make up and legitimizes his notion of 'law' and more. For our discussion in Chapters 2 and 3, we learn that the ultimate backing that institutions of law provide to the construction of hybrids and chimeras has been critical in securing public trust and legitimacy. This hybridization of law and disciplines is also important in illustrating a relationship between law and medical science(s). Consistent with the notion of co-production that has been put forward by Sheila Jasanoff, both law and discipline construct and reinforce dominant social understandings of security, progress and collective good.[871] In deliberating over the varied applications of human embryonic stem cell research, a holistic understanding of scientific development would not be possible without simultaneously engaging with legal facticity in the distinctions between subject and object, permissible and non-permissible, human and non-human, property and non-property, and so forth. From this standpoint, the law is arguably no more distinct as a cultural institution than medical science(s).[872]

Moving beyond Foucault's limited construction, there is a broader manner to think about law. Hunt and Wickham indicate that law is increasingly concerned with 'normative formation', so that the phenomenon of normalization is not the exclusive domain of disciplinary power. A more adequate account needs to stress a persistent increase in the range, scope and detail of legal intervention that produces a general movement towards an expanding legalization and

871 Sheila Jasanoff, Making Order: Law and Science in Action. In Edward J. Hackett, Olga Amsterdamska, Michael E. Lynch, Judy Wajcman, Wiebe E. Bijker, *Handbook of Science and Technology Studies*. Cambridge MA: MIT Press, 2007 (3rd Edition), pp 761-789, at 772.

872 See generally: Mark Kelman, *A Guide to Critical Legal Studies*. Cambridge MA: Harvard University Press, 1987.

juridification of social life.[873] In a more recent contribution, Rose, O'Malley and Valverde similarly argue that governmentality *is* intellectual innovation rather than some blue-print of dominance that "falls out of the clear blue sky."[874] They argue that it is questionable that one should find a single form of governance (or government) that is at once coherent, consistent and absolute. Rose, O'Malley and Valverde express the view that "the assemblage nature of government always suggests that rationalization – the process of rendering the various elements internally consistent – is never a finished process. Rationalities are constantly undergoing modification in the fact of some newly identified problem or solution, while retaining certain styles of thought and technological preferences."[875] In Chapter 4, we find legal reasoning to be applied in drawing relationalities through comparisons that cuts across the domains of law and discipline. On this point, Annelise Riles makes a pertinent observation that the rationales of comparative law have for a time been brought into the service of state, and clearly not in a 'punitive' sense.[876] As we have also considered in Chapter 5, a combination of legal and other rationalities could be viewed as technologies of risk and precaution that become the very basis of governance, in addition to studying knowledge forms and culture.[877] In all three genres, Rose *et al.* argue that one should eschew from static abstraction, and focus instead on analyzing the "technologies" that govern habits, moral and ethics.[878] An attempt at implementing a more holistic governmentality by many bioethical bodies, including the BAC, has taken the form of the ethical, legal and social implications (ELSI) approach to evaluating biomedical

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873 Alan Hunt and Gary Wickham, *Foucault and Law: Towards a Sociology of Law as Governance.* Pluto Press: Finland, 1994, at 66.

874 Nikolas Rose, Pat O'Malley and Mariana Valverde, Governmentality, *Annual Review of Law and Social Science* (2006) 2:83-104, at 92.

875 *Ibid*, at 98.

876 Annelise Riles, *Rethinking the Masters of Comparative Law*. Oxford & Portland: Hart Publishing, 2001, at 6.

877 Nikolas Rose, Pat O'Malley and Mariana Valverde, Governmentality, *Annual Review of Law and Social Science* (2006) 2:83-104, at 95-6.

878 *Ibid*, at 97.

developments. We continue to consider the contribution of law at this normative level, which I argue to be a juridification of social life.

6.4 Juridification in ELSIfication

Governmentality in biomedical research has perhaps been most explicitly and profoundly expressed and experienced in various initiatives that are directed at addressing the ethical, legal and social implications (ELSI) that arise from the research. In their study of ELSI initiatives attached to major science programs in Canada, José Julián López and Janet Lunau illustrate two specific modes of legal reasoning – analogy and reflective equilibrium – that have been applied in the works of two of the most prominent ELSI legal scholars.[879] Analogical reasoning is the method used to determine an outcome of a new situation by reference to relevant precedents (typically relating to similar situations). Reductionism is arguably the greatest weakness, as well as strength, of this approach as the ability to gloss over novelty and differences enables the generation of closure (or finality).[880] In contrast, reflective equilibrium (popularized by John Rawls) seeks to generate coherence in moral theorizing by simultaneously pitting general theories, principles and considered judgments against each other. Unlike moral theory however, there are fixed parameters in legal reasoning, primarily because legal inquiry is not an open-ended process. Instead, "law is a social technology of dispute resolution, [where] the *telos* of legal reasoning as a knowledge producing practice is to invoke the authoritative sources internal to its practice that will facilitate a resolution".[881] When ELSI questions become juridified

879 José Julián López and Janet Lunau, ELSIfication in Canada: Legal Modes of Reasoning, *Science as Culture* (March 2012) 21,1: 77-99.
880 *Ibid*, at 89.
881 *Ibid*, at 94.

through their subsumption to modes of legal reasoning, the 'expressive capacity' and 'cultural power' of the law is down upon to produce closure. This in turn has been found to "resonate with the ELSI field's desire for the practical advanced assessment of technological development".[882]

In Chapter 2 to 5, we have similarly considered how legal reasoning has been applied in the 'ELSIfication' of biomedical research policies in Singapore. The capability of the law to transform messy and complex phenomena into depoliticized and calculable cases that are amenable to governance is well recognized.[883] Juridification in this sense tends to have a negative connotation in its reference to the 'colonization' of social relationships in legal terms.[884] A key concern is that when actions become guided by the logic of a legal rule or general legal claim, it creates a false sense of finality in the purported existence of general social consensus and consistency with the requirements of justice.[885] In relation to children's rights, concerns have been expressed over the potential risks that juridification might result in dichotomized social relations, especially in educational relationships. In addition, a legal rule could be too limiting through possible exclusion of other factors (eg age, ethnicity, economic and religious background) that influence the construction of children's rights.[886] This 'crowding out' by law of other social and political norms and considerations (described as "legal pollution") presents the growth of law as uncontrolled and harmful, particularly where juridification fails to meet its

882 *Ibid*.

883 Jurgen Habermas, *The Theory of Communicative Action: Lifeworld and System: A Critique of Functionalist Reason* (Trans. Timothy McCarthy), Vol. II. Boston: Beacon Press, 1987, at 365; Pierre Bourdieu, The force of law: towards sociology of the juridical field, *Hastings Law Journal* (1987) 38, 4: 814-853 at 830.

884 Alan Hunt, Foucault expulsion of law – toward a retrieval, *Law and Social Inquiry* (1992) 17, 1: 1-38.

885 Tom Cockburn, Children and the feminist ethic of care, *Childhood – a Global Journal of Child Research* (2005) 12, 1: 71-89.

886 Didier Reynaert, Maria Bouverne-De Bie and Stijn Vandevelde, Between 'believers' and 'opponents': Critical discussions on children's rights, *International Journal of Children's Rights* (2012) 20: 155-168, at 161-162.

intended goal of regulation.[887] There is a further concern that directive-styled (ie command-and-control) and comprehensive regulation could divert targets of regulation (such as researchers and doctors) from norm compliance to law compliance, thereby undermining their desire to concern themselves with the normative spirit of the law. In other words, juridification could result in the displacement of professional or communal norms by legal ones, with detrimental effect on professional or communal practices. Such a development could further encourage the pursuit of self-interest and disincentivise trustworthiness and ethical reflexivity.[888] To varying extents, these concerns have already been observed in the IRB review process.[889]

Gordon Silverstein adopts a slightly different definition of 'juridification' to mean the degree to which a debate and the product of that debate in a political process came to be dominated, structured, framed and constrained by a certain part (ie law) of that process. He attributed this in one part to the increasing role of, and reliance upon, judicial decision making, legal reasoning, and legal language, and in another part to the legalization and formalization of political discourse and of the political process itself.[890] Evaluating developments in the US over the past 50 years, he observes that law and politics have become more intertwined. However, juridification is not an all-or-nothing proposition, but more a question of degree. The judicialization of policy can be advantageous if it is the only viable means to achieve certain goals (eg overcoming struggles

887 Gunther Teubner, Juridification – Concepts, Aspects, Limits, Solutions. In Gunther Teubner (ed), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labor, Corporate Antitrust and Social Welfare Law*. Berlin: Walter de Gruyter & Co., 1987, pp 3-48, at 3.

888 Robert Gatter, Human Subjects Research and Conflicts of Interest – Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest, (2003) *Emory Law Journal* 52: 327-401, at 388-389.

889 Marie-Andrée Jacob and Annelise Riles, The New Bureaucracies of Virtue, *Political and Legal Anthropology Review* (2007) 30, 2: 181-191; and Marie-Andrée Jacob, Form-made Persons: Consent forms as Consent's Blind-Spot, *Political and Legal Anthropology Review* (2007) 30, 2: 248-268.

890 Gordon Silverstein, Law's Allure in American Politics and Policy: What It Is, What It is Not, and What it might yet to be, *Law & Social Inquiry* (Fall 2010) 35, 4: 1077-1097, at 1080-1081.

over abortion), but less so if it prevents the production of creative solutions through institutional interaction. [891] Whether juridification is beneficial would depend on understanding how institutions interact and constrain each other.[892]

From the discussion above, I understand 'juridification' to mean the application of one or more forms of legal rationality to a social phenomenon. Teubner's use of the term suggests that legal rationality would necessarily crowd out other forms of rationalities and so reduce a social phenomenon to a legal one (hence the depiction of juridification as legal pollution).[893] My research findings do not support this reading of juridification. If this was true, then as Teubner concludes, the role of reflexive law should primarily be integrative.[894] In addition, Teubner seems to assume that the 'juridical' component can always and readily be isolated so that the danger of juridification is also a question of "relative dominance" between legal rationality and other competing rationalities. In theory, the ELSI label suggests that the ethical, legal and social components could be neatly segregated and evaluated. This has not been my experience at all. I have attempted to show in all the earlier Chapters of this dissertation that not only are ethical and legal rationalities *not* neatly demarcated, they form an infungible composite with the ethical, the scientific, the medical and the social, the last of which being a sort of incomplete remainder that accentuates the artificiality of the various forms of epistemic fractioning. As explained in Chapter 1, my deployment of the term 'juridification' simply suggests the application of legal norms, rationalities, techniques and practices in sustaining a particular understanding or

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891 *Ibid*, at 1082.

892 *Ibid*, at 1093-1094.

893 Gunther Teubner, Juridification – Concepts, Aspects, Limits, Solutions. In Gunther Teubner (ed), *Juridification of Social Spheres: A Comparative Analysis in the Areas of Labor, Corporate Antitrust and Social Welfare Law*. Berlin: Walter de Gruyter & Co., 1987, pp 3-48, at 38.

894 *Ibid*, at 40.

knowledge claim. I have explained in Chapters 2, 3 and 4 how they have contributed to the construction of hybrids and chimeras. Here, juridification neither precluded *all* other forms of rationality (although it did exclude certain types of rationality such as religious ones), nor provided permanent closure. Much to the contrary, and consistent with the STS notion of co-production, other forms of rationalities, such as ethical and medico-scientific ones, have been drawn upon to sustain the claim and to maintain epistemic openness. At the same time, I am not proposing that juridification is nothing more than a norm. François Ewald proposes this in drawing a distinction between juridical (ie the institution of law as the expression of sovereign power) and law (as formulation of norms).[895] But if, as Foucault prognosticates, demise is the outcome of the juridical, then the law must eventually be subsumed within a norm. Such a viewpoint does not sufficiently account for the distinct characteristics of legal institutions and rationalities. To be sure, I am not thereby saying that they are so distinct as to become an autopoietic entity. Rather, my argument is that the other extreme of reductionism in the representation of law should be similarly avoided.

There is in reality no clear demarcation among 'governed', 'self-governed' and 'governor', although these are helpful as a starting point and general heuristic references. To my mind, the governed/self-governed/governor formulation runs along the same conceptual strand as Marilyn Strathern's audit/policy/ethics triad. In this regard, she considers the social and cultural worlds are brought closer together with the language of ethics, and both audit and ethics are structuring

[895] François Ewald, Norms, Discipline, and the Law, *Representations* (1990) 30:138-161, at 138-139. Ben Golder and Peter Fitzpatrick provide convincing arguments on why such an approach is itself limiting and inconsistent with Foucault's analytical agenda. See Ben Golder and Peter Fitzpatrick, *Foucault's Law*. London and New York: Routledge, 2009, at pp 102-107.

social expectations in such a way as to create new principles of organization.[896] Drawing from Annelise Riles, Strathern observes that the way in which ethics, audit and policy describe themselves point to their implication in one another, so if audit/policy/ethics is really a triad of emergent practices or a set of related trajectories, then audit (ie accountability in a widely acceptable and mobile cultural form), is just one among many changing features of social life. Applying Strathern's rationale to Hunt and Wickham, the governed/self-governed/governor formulation will ultimately relate back to governmentality. And this conclusion she did state.

Referring to Shore and Wright, Strathern indicates that the 'policy' of interest to anthropological enquiry is an arena where governments re-invent society and promote cultural change. For instance, the New Right discourses of the 1980s embedded certain conceptualizations of the 'individual' (person) in a nexus including 'freedom,' 'market', 'enterprise' and 'family.'[897] It incorporates a particular vision of the way in which people relates to the state. It was a relationship which could be mediated by, or translated into, ideals of how people would relate, as individuals and family members, to the 'market', and new 'customers' were invented.[898] Government defined the state's role as guardian or guarantor of value so that 'performance', which commonly took the form of good practice and good financial management, was subject to 'selectivity' based on 'measures' used as a bureaucratic yardstick. Auditing becomes an example to add to all the myriad ways in which people govern themselves and the social state gives way

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896 Marilyn Strathern, Accountability…and ethnography. In Marilyn Strathern (ed), *Audit Cultures: Anthropological studies in accountability, ethics and the academy*. London: Routledge, 2000, pp 279-304, at 281.

897 *Ibid*, at 288.

898 Strathern notes (*Ibid*, footnote 16, at 299) the critique of Heelas and Morris's *The Values of the Enterprise Culture: the Moral Debates* (1992): the traditional enterprise virtues of responsibility and discipline had been eclipsed by the runaway success of promoting consumerism and the ethic of wealth creation. These are in turn made visible by separate organs dedicated to accountability and quality control.

to the enabling state.[899] In promoting value for money and economic efficiency, persons and organizations are being assisted to provide public assurance of their viability. When, as in higher education, 'individuals' become conscious of themselves as 'performers', seemingly 'in control' of their performance, the bureaucratic reflexivity involved is part of their relationship to the enabling state. For Strathern then, "'Governmentality' is presumed by attributing agency to the governed."[900] However, the recent financial crisis makes clear the centrality of the state in shoring up a broken financial system and in distribution of costs across generations.

6.5 On Regulationism

In thinking about governmentality as encompassing both legal institutions (or if a distinction has to be made, the juridical) and legal norms and practices made explicit in their underlying rationalities, I have applied ANT in an attempt to map out a particular network of power across spatial, material, social and ideological dimensions. For ease of reference, I refer to this network configuration as a regulationism. As Sheila Jasanoff observes, I hope to "add nuance to Foucault's grand narrative of governmentality by revealing culturally specific ways in which modern societies come to know the subjects who are governed."[901] At one level, this research investigates the relationship between science and law, the outcome of which I have discussed above. At a broader level, it seeks to map the interrelations among the different modalities of

899 Strathern refers to Nikolas Rose's *Powers of Freedom: Reframing Political Thought*. Cambridge: Cambridge University Press, 1999: *Ibid*, at 289.

900 *Ibid*, at 290.

901 Sheila Jasanoff, Making Order: Law and Science in Action. In Edward J. Hackett, Olga Amsterdamska, Michael E. Lynch, Judy Wajcman, Wiebe E. Bijker, *Handbook of Science and Technology Studies*. Cambridge MA: MIT Press, 2007 (3rd Edition), pp 761-789, at 779.

power in a specific bioethical policy environment. In Chapter 1, I have set out the reasons why ANT is effective as a mode of inquiry that renders visible connections and interactions that are not otherwise so. I want to emphasize here the importance of rendering visible the 'nuances' of governmentality that Foucault has glossed over (in his earlier works at least). In framing and pitting law as sovereign power against non-sovereign power, it becomes impossible in this analytic to understand how these different modalities of power interact and the way that they shape (and co-produce) each other. Latour's criticism of Durkheim's dualism of "self-contained individuals" fighting for a place in the "self-contained society" as an ultimately sterile analysis could also be applied to this aspect of Foucault's analytic.[902] As Latour describes the problem, "we have lost the precise conduits through which what we call "the whole" actually circulates".[903] Another point that I want to highlight is that in understanding how different modalities of power interact by mapping the network of material, social, institutional and ideological nodes in the context of this research, the 'space' within which co-production occurs is also explicated. The spatial dimension of power relations has been the subject of Latour's earlier works.

Bruno Latour shows the link between politics and expertise in his account of a fundamental transformation brought about by the discovery of microbes by Louis Pasteur, and the alliance between his followers (referred to as Pastuerians) with the hygienists.[904] In addition, he indicates that the laboratory is the 'limited space' of expertise that the Pasteurians created to deal with people who oppose them. In this relational 'space' where they are experts (one can perhaps read

902 Bruno Latour, Networks, Societies, Spheres: Reflections of an Actor-Network Theorist, *International Journal of Communication* (2011) 5:796-810, at 803.
903 *Ibid*, at 805.
904 Bruno Latour and John Law, *The Pasteurization of France.* Cambridge MA: Harvard University Press, 1988.

this as a Kuhnian paradigm), the strength of their opponents are reduced and it is also in this 'space' that Pasteurians create a world perceived under their distinct worldview. In addition, Pasteur sought to address practical issues that served to strengthen the Pasteurian movement. He observes: "Why did Pasteur gain strength in the laboratory? He did so because there, as in every laboratory, phenomena are finally made smaller than the group of men who can then dominate them."[905] Latour's analysis points to the significance of the relationship between physical and ideological spaces, which is often overlooked. Policy-makers that I have interviewed often describe Singapore's regulatory approach to the life sciences as 'light-touch' and 'phased'. One interviewee explained that there are not many legislation on biomedical research, and even these are not only general in character, but also defined and applied within relatively fixed parameters or spaces. As such, the regulatory approach could also be seen as locational, and could gain substance over them.[906] A contact added that regulatory development is mirrored in the 'phased' construction of the Biopolis, the physical location where much of life sciences research is being done.[907] Rather than think very generally about governmentality as the imposition of certain abstract disciplinary or state power, it may be helpful to conceptualize them as localized interventions in the generation of long-term medical knowledge and practices. Philip Howell presents such an analytical approach in his historical study on the governance of prostitution, which he argues is a politics of place, and a localized intervention in the economy of sex – a strategy above all of containment – where particularities of place were taken into account. He

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905 *Ibid*, at 74. This is most evident in his chart (at 267) of Pasteur's career as rectilinear, that progresses from crystallography to micrography to veterinary medicine to fermentation to biochemistry and ultimately to "the entire world." Latour indicates that while Pasteur had a hand in starting up these and other new fields, he left them to others to be developed as distinct disciplines (at 68-9). For instance, Koch had the job of classifying and describing microbes and their relationship with particular diseases (at 69). This also affected Pasteur's choice of diseases such as viruses that his method did not elucidate (at 70).

906 Interview with Mr. Charles Lim, BAC Member and Principal Senior State Counsel and Parliamentary Counsel, Attorney-General's Chambers, 14 January 2008.

907 Interview (CR2), 10 September 2008.

study covers four regulationist regimes in the towns of Liverpool and Cambridge, in the fortress of Gibraltar and in the colony of Hong Kong.[908]

Regulation and regulationism in Howell's research refer to the measures introduced at various times, various places, to control the perceived dangers of uncontrolled female prostitution – mainly public disorder and the propagation of sexually transmitted diseases. Entailed in regulationalism is the combination of identification, inspection and incarceration, and the rationale that "prostitution might be governed".[909] Modern France has been described as regulationism's 'home country' and is said to have created the 'ideal form' of regulationist regimes that comprised systems of licensed brothels, the networks of venereal dispensaries, and the establishment of *police des moeurs*. Regulationists further regarded their position as the expression of modern rational, hygiene principles and the application of enlightened public health measures.[910] In Britain, the Contagious Diseases Acts ('CD Acts') were responses to British disasters in the Crimea, where concerns arose over the prevalence of disease among military men. Howell indicates that other important factors are a new sanitary science and the prestige of the military at that time.[911] The first of the CD Acts was passed in 1864 to protect the health of soldiers and sailors in eight garrison and dockyard towns in England. The 'common prostitutes' identified by police and magistrates could be subject to medical examination and detained if found to have a venereal disease. A replacement Act followed in 1866, periodical medical examination was added for the first time and the power of magistrates was replaced by government appointed surgeons. Following minor amendments in 1868, the third CD Act was

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908 Philip Howell, *Geographies of Regulation: Policing Prostitution in Nineteenth-Century Britain and the Empire*. Cambridge: Cambridge University Press, 2009, at 2.
909 *Ibid*, at 3.
910 *Ibid*, at 7-8.
911 *Ibid*, at 15.

enacted in 1869 – but which time a complex administrative structure was in place.[912] He observes:[913]

> The three CD Acts were constructed from a range of medical, legal, military, political and philanthropic institutions whose workings cannot be reduced to any simple formula of disciplinary power, still less conjured up from the abstractions of sanitary discourses or medico-moral ideology. Each Act was really a kind of *assemblage*, partly grounded in well-thought-out sanitary principles but equally as much the result of pragmatic manoeuvres designed to satisfy this range of interests. Each was thus no more or less than a 'workable system of regulation'.

In Victorian Cambridge, a proctorial system was introduced whereby University authorities managed prostitution through a careful strategy of tolerance in one part of town, and repression of street prostitution. Women who were regarded as prostitutes and their male undergraduate clients were subject to some level of monitoring. Oxford had a similar regulationist system – both of which assumes that young undergraduates could be easily tempted, but those who fell into sin could be corrected and was self-correctable.[914] Howell indicates that regulationism in Oxford and Cambridge would have had an important influence over the construction of British and imperial masculinity in the Victorian and Edwardian era, "an identity inseparable from the homosocial and heterosocial parameters of the undergraduate experience, and thus inseparable from questions of both gender and sexuality."[915]

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912 *Ibid*, at 28.
913 *Ibid*, at 38.
914 *Ibid*, at 130-131.
915 *Ibid*, at 151.

The value of thinking about regulationism not only as particular configurations of power modalities in the way that material and social nodes are linked, but also as 'spaces' within which such interactions are sustained is that it provides a better account of the dynamism of governmentality. The conduits that we find are continuously made and re-made within spatial-temporal intervals, as significant degrees of learning and responsiveness are very much part of policy work. These 'spaces' are also another way of recognizing the inevitability of fractals, as Marilyn Strathern observes, because ethnographic representations are always partial.[916] In other words, the 'spaces' in regulationism are explicit recognition of epistemic limits, while simultaneously illustrating a particular power-complex at work. To summarize our discussion so far, I have attempted to re-cast Foucault's notion of law along a trajectory that he set out in his discourse on governmentality, but otherwise did not develop further. With other (particularly STS) scholars, I argue that it is important to understand law holistically, in terms of both juridical institutions and legal rationalities and practices, as well as inter-relationally with other modalities of power (particularly in its relationship with ethics and medical science(s) as a discipline). One modality of power responses and co-produces the other, and they collectively co-construct and sustain epistemic claims and 'things', such as hybrids and chimeras in biomedical research. As we have seen, the nature of state has itself altered from coercive power (by Foucault's early analysis) to an innovative one. Within this power complex, I define the contribution of law as 'juridification'. Given the nature of co-production, my research detracts from those who present this term negatively. In studying this power-complex, I have (again with STS scholars) argued that ANT is an effective mode of inquiry that not only explicates a particular configuration of the modalities of power in terms of material and social nodes, but also the 'spaces' within which change (through re-configuration for instance) is possible. I have used the term 'regulationism'

916 Marilyn Strathern, *Partial Connections*. Savage ML: Rowman & Littlefield Publishers, at xxiv and 53.

to depict a particular configuration (and space), which I hope could serve as a more effective analytic to study and account for the regulation of human embryonic stem cell research.

6.6 The BAC as a Pseudo-Juridical Entity

I conclude this dissertation by returning to consider my key ethnographic subject, the BAC. I argue that it is a pseudo-juridical entity, and in 'pseudo', I mean that it is not juridical in a literal or formal sense (ie a political title to that effect). However, in applying the analytic of regulationism, it is argued that the BAC bears juridical features in at least four respects: (1) Real links to state and juridical institutions; (2) Pervasive use of legal norms, rationalities, techniques and language; (3) Institutional forms which are characteristics of juridical institutions; and (4) Sociality that is akin to that of law (considered in relation to the 'space' entailed in regulationism).

Links to State and Juridical Institutions

For some time now, MOH has expressed its intent to create a legislative framework on biomedical research. Almost all researchers that I spoke with in the course of my research, whether in Singapore or overseas, have expressed concern over this move. They seemed convinced that legislation will smother research. Curious enough, it is already an implicit requirement for all biomedical research in Singapore to undergo some form of ethics review. While some researchers still complain about this process as a burden to research, most have accepted it as a 'necessary evil'. In a significant number of cases, ethics review is either managed

by or otherwise involve lawyers. Some lawyers told me that they consider ethics review to be a sub-field of administrative law. An analogy could perhaps be drawn between administrators involved in ethics review (or perhaps even those working on bioethical policies like myself!) with Annelise Riles's protagonist, Mr. Sato, who represents the army of 'back office' or 'documentation' people.[917] But unlike financial institutions, hospitals (where IRBs here are mainly based) and medical qualified researchers are closely supervised by MOH – a critical part of an organ of the state. The BAC is itself proximate to state power in having a direct communicative link to the SCLS (whose chair has since been elected the President of the Republic of Singapore), as well as to the Law Reform Division of the Attorney-General's Chambers. While the recommendations and guidelines of the BAC may not have the formal force of law, it has real regulatory effect: first, they prescribe standards of conduct and generate expectations that shape practices and conduct; second, they present measures that are introduced for the containment of 'unethical' behavior – whether in relation to research ethics or research integrity – and constitute the 'good' and the 'acceptable'; and third, there may be punitive consequences for non-compliance. The link that the BAC has to law enforcement agencies is expected to be even clearer with the prospective enactment of a proposed legislation on biomedical research. Hence it is ironic that whereas medicine and science have attempted to exclude the state from their enterprises, much like the creation of a 'free market' environment, this research has found that the state remains at the core of much of their activities.

[917] Annelise Riles, *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011, at 36-38.

Like Annelise Riles, I have attempted to explicate the techniques that have been deployed in the policy construction of 'hybrids' and 'chimeras' in Singapore.[918] We have considered how 'hybrids' and 'chimeras' served as metaphorical placeholders, the role of documents in establishing relationalities and in scripting, the instrumental and substantive use of ethical and legal theories and analogies and as anticipatory knowledges, such as those relating to a variety of risks and other 'political technologies of preparedness'. These techniques, as Riles observes, also have the effect of acting in the 'meantime'.[919] From my interactions with policy workers in the various ministries, they have a consistent view that legislation should be generic and not readily revisable. In fact, I was taken to task for reporting in an official document that a relatively senior policymaker considered a certain legislation to be 'archaic'. This was somewhat of a surprise for me, as Singapore is effectively ruled by a single political party and it would not be difficult to alter legislation, when necessary. However, legislation appears to have the character of making explicit certain 'truths', and hence should not be quickly altered when enacted. In contrast, regulations and policies that are not seen as subject to this constraint. They (and their implements – i.e. techniques) draw deeply on notions of 'risks' and 'precaution' as common fund of knowledges (discussed in the previous Chapter). In this space that is sustained by law and disciplinary powers, an incremental build-up of regulatory and anticipatory knowledges of the known, the currently unknown and the unknowable, is enabled – often presented as a political technology of preparedness. On first blush, juridification in the deployment of legal norms, rationalities, techniques and language is difficult to detect. But on deeper analysis, we detect the

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[918] *Ibid*, at 228.
[919] *Ibid*, at 229.

slow, halting advancement of legal texts that Latour considers to be the critical means by which social facts are made by the Conseil through linking inscriptions of facts and legal principles.[920] Relating this back to Latour, the BAC is arguably similar to the *Conseil d'État* in that it is effectively a mixed political-regulatory body.

Juridical Forms

Taking a broader view, the policy setup centered around the BAC (not to mention its operations) resembles a judicial structure. As we have seen, normative prescriptions from the BAC are practically binding on all IRBs in Singapore. IRBs in turn adjudicate on the ethical acceptability of research proposals. There is at present no appeal mechanism to the BAC, but this has been debated in the BAC and elsewhere. From my interviews, it seems that the main obstacle to implementing such a mechanism is more a matter of resource limitations. Considering the work of the BAC, it is difficult to deny the very fundamental influence of the law. Although Professor Lim Pin (an endocrinologist) has been the Chair of the BAC, the key sub-committees and working group that have been responsible for all its reports to date were chaired by either a senior judge or a law professor.[921] Judge Magnus, who was responsible for the BAC's SC Report, has since succeeded Professor Lim as the second Chairman of the BAC from 2011. All legally trained members of the BAC have indicated that legal skills in mediation, adjudication

920 Bruno Latour, *La fabrique du driot: Une ethnographie du conseil d'État* [The factory of law: an ethnography of the Conseil d' d'État]. Paris: La Découverte, 2002, at 80.

921 Both Senior District Judge Richard Magnus (interview on 18 April 2009), who chaired the Human Stem Cell Research Sub-Committee, and Professor Terry Kaan (interview on 16 June 2009), who Chaired the Human Genetics Sub-Committee, said that the legal training has enabled them to mediate differences in an impartial manner.

and securing a reasonable outcome to ethical contentions have been important to meeting their responsibilities on the Committee.

In this dissertation, I have also attempted to present the ways in which the BAC made representation, provided opportunities to be heard, gave performative demonstrations of evidence, recorded narratives and outcomes. All of these are commonplace features of a courtroom drama and consistent with the requirements of legal norms. Effective representation requires an engaging narrative that first and foremost represents relevance. In his study of a report of the NAS relating to diet, nutrition and cancer, Stephen Hilgartner argues that various means of information control are entailed in the creation and management of a stage. Such controls are akin to frame selection in effect. Institutions and their work procedures regulate access to information much like a backstage that manages the flow of persons, speech and documents. More importantly, they serve to structure relations between experts and publics, and are devices "of *constituting* performers and audiences with particular capabilities (and enforced inabilities) of speech and perception."[922] In a sense, the HA Consultation Paper may perhaps be likened to a stage (courtroom drama?) upon which one narrative of stem cell science and technology is presented to a diversely composed audience which might not have had an immediate interest in the subject. In the context of our discussion, the BAC (and its institutional procedures relating to the consultative process and its documents) has been instrumental in co-producing a public vis-à-vis stem cell science and technology. It may be further argued that, just as the enactment of a stage and performance would precede an audience, the BAC, through the instrumentality of the consultation paper, played a critical part in producing a 'public' through

[922] Stephen Hilgartner, *Science on stage: expert advice as public drama*. Stanford: Stanford University Press, 2000, at 147 (emphasis in original).

active engagement with it. This is perhaps no different from how other social systems, such as the courts, have produced their own 'publics' (concerned with rights and obligations).

Sociality

Unlike a courthouse, the BAC is not primarily concerned with dispute resolution. This key distinction means that juridification applied to this effect, need not blot out other rationalities. Practically, the BAC is institutionally more comfortable with indeterminacies and paradoxes.[923] For instance, in soliciting feedback from the public, the accounts provided by the BAC in its HA Consultation Paper are quite different from the sort of narratives that have been used to argue for strong investment in science and technology. In other words, it is a narrative somewhat different from the futuristic deterministic account such as the 'greyist' narrative deployed to push for institutional reform.[924] Instead, they are more open-ended, positive and deployed as means by which citizens could contribute creatively to technological assessment, quite similar to the 'science fictions' that Clark Miller and Ira Bennett envisage.[925] The BAC's approach follows a broader trend of public engagement in the US and Europe, and such 'science fiction'-like narratives are tools that help the public engage more positively and intimately with scientific and

923 Drawing on autopoiesis theory, Teubner explains that the components of a legal system (being actions, norms, processes, identity, legal reality) are seen as cyclically linked with each other in multifarious ways. Self-reference, paradoxes and indeterminacies are overcome by declaring the circularity to be a problem of legal practice, rather than legal thought, thereby ensuring the independence of its cognition. Gunther Teubner, And God Laughed…Indeterminacy, Self-Reference and Paradox in Law, *German Law Journal* (2011) 12: 376-406, at 385-6.

924 Martijn van der Steen, Ageing or silvering? Political debate about ageing in the Netherlands, *Science and Public Policy* (October 2008) 35, 8: 575-583.

925 Clark A. Miller and Ira Bennett, Thinking longer term about technology: is there value in science fiction-inspired approaches to constructing futures? *Science and Public Policy* (October 2008) 35, 8: 567-606.

technological futures;[926] in addition, the UK government's 'GM Nation' exercise has been described as occasions "where writers might be asked to develop multiple stories and dialogues that could be shared with the public alongside more technical reports" to be used when citizens "meet and dialogue about their preferences with regard to genetically modified organisms".[927]

Rather than attempt to isolate the 'law' from bioethics as a composite, I have moved away from the study of law an object. While some degree of essentialism is unavoidable, I have attempted to study how legal norms, techniques, practices and spaces have operated on the periphery, rather than as a field of habitual knowledge[928] or as an autopoietic institution.[929] In many ways, bioethics is similar to governance of financial derivatives in Annelise Riles's study.[930] As a lawyer working in the area of bioethics, legal rationalities, techniques and norms are everywhere, and nowhere. This is perhaps most evident as scholars remain divided as to whether the law *is* bioethics or otherwise totally separable.[931] In the analytic of regulationism, I have attempted to illustrate how the law has been capable of being other to itself, as well as its responsiveness to other modalities of power. As Ben Golder and Peter Fitzpatrick have observed elsewhere, "law is central to an experience of modernity… [and] represents a key modality of our sociality, of our continuate being with each other. Through its ability to combine iteratively a determinate securing of limits and a responsive regard to the disruption of those limits and their re-

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926 Miller and Bennett observe: "…the US government has built public comment periods and public hearings into regulatory decision-making processes, while European governments and universities have pioneered novel forms of public engagement such as consensus conferences and *cafés scientifiques*": *Ibid*, at 599.

927 *Ibid*, at 605.

928 Pierre Bourdieu, The Force of Law: Toward a Sociology of the Juridical Field (translated by Richard Terdiman), *Hastings Law Journal* (1987) 38:805-853.

929 Niklas Luhmann, *A sociological theory of law* (translated by E King and M Albrow). London: Routledge and Kegan Paul, 1985.

930 Annelise Riles, *Collateral Knowledge: Legal Reasoning in the Global Financial Markets*. Chicago and London: University of Chicago Press, 2011.

931 Tom L Beauchamp, Informed Consent: Its History, Meaning, and Present Challenges, *Cambridge Quarterly of Healthcare Ethics* (2011) 20: 515-523, at 518.

formulation, law provides an opening to futurity."[932] This dissertation is not intended to be a critique of law or an argument for law's further inclusion or exclusion in bioethics. Instead, I have attempted to demonstrate how the law as a social technology of dispute resolution has contributed to the production of bioethical knowledge and practices, through means that include rendering the future knowable and calculable. [933] The symbols, concepts and techniques in law have also enabled the creation of a governance space. In Singapore, bioethical regulationism commenced with the juridification of nascent life – the 'embryo' and 'pre-embryo'. Bioethical knowledge has since advanced, from when 'personhood' begins, to what makes a 'person'. The process has encapsulated collaborative linkages across different social systems and powers, including law.

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932 Ben Golder and Peter Fitzpatrick, *Foucault's Law*. London and New York: Routledge, 2009, at 125.

933 As José Julián López and Janet Lunau explain: "Whereas the other disciplines might be able to speak to the ethical, legal or social implications in isolation, law can speak to the medical-ethical-legal-social thing in tis compound thingness. Juridification, after all, refers to 'a form of reasoning that subjects the plural disciplines and identities of social life to the homogenous and hierarchical norms of a self-defining and increasingly asocial discourse of law.'" José Julián López and Janet Lunau, ELSIfication in Canada: Legal Modes of Reasoning, *Science as Culture* (March 2012) 21, 1: 77-99, at 82.

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